

**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 June 30, 2023

OR

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number: 001-38693

**Allogene Therapeutics, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

82-3562771  
(I.R.S. Employer  
Identification No.)

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

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 checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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

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

As of July 31, 2023, the registrant had 167,626,365 shares of common stock, \$0.001 par value per share, outstanding.

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**PART I: FINANCIAL INFORMATION****Item 1. Financial Statements**

**ALLOGENE THERAPEUTICS, INC.**  
**Condensed Consolidated Balance Sheets**  
*(Unaudited)*

*(In thousands, except share and per share amounts)*

	June 30, 2023	December 31, 2022
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 154,758	\$ 61,904
Short-term investments	337,204	455,416
Prepaid expenses and other current assets	10,139	11,504
Total current assets	502,101	528,824
Long-term investments	52,586	59,151
Operating lease right-of-use asset	80,314	83,592
Property and equipment, net	106,386	112,839
Restricted cash	10,292	10,292
Other long-term assets	9,382	9,564
Equity method investment	9,910	12,817
<b>Total assets</b>	<b>\$ 770,971</b>	<b>\$ 817,079</b>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 10,229	\$ 13,890
Accrued and other current liabilities	44,263	39,743
Deferred revenue	229	885
Total current liabilities	54,721	54,518
Lease liability, non-current	91,821	95,122
Other long-term liabilities	1,523	1,569
<b>Total liabilities</b>	<b>148,065</b>	<b>151,209</b>
Commitments and Contingencies (Notes 6 and 7)		
Stockholders' equity:		
Preferred stock, \$0.001 par value: 10,000,000 shares authorized as of June 30, 2023 and December 31, 2022; no shares were issued and outstanding as of June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value: 400,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 167,133,664 and 144,438,304 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	167	144
Additional paid-in capital	2,039,263	1,911,632
Accumulated deficit	(1,412,673)	(1,235,980)
Accumulated other comprehensive loss	(3,851)	(9,926)
Total stockholders' equity	622,906	665,870
<b>Total liabilities and stockholders' equity</b>	<b>\$ 770,971</b>	<b>\$ 817,079</b>

*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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Collaboration revenue - related party	\$ 44	\$ 86	\$ 96	\$ 147
Operating expenses:				
Research and development	62,038	57,171	142,276	117,327
General and administrative	18,524	19,509	37,408	39,406
Total operating expenses	80,562	76,680	179,684	156,733
Loss from operations	(80,518)	(76,594)	(179,588)	(156,586)
Other income (expense), net:				
Interest and other income, net	3,778	315	5,837	807
Other (expenses) income	(1,249)	1,492	(2,942)	1,142
Total other income, net	2,529	1,807	2,895	1,949
Net loss	(77,989)	(74,787)	(176,693)	(154,637)
Other comprehensive loss:				
Net unrealized gain (loss) on available-for-sale investments	2,083	(2,223)	6,075	(8,905)
Net comprehensive loss	\$ (75,906)	\$ (77,010)	\$ (170,618)	\$ (163,542)
Net loss per share, basic and diluted	\$ (0.53)	\$ (0.52)	\$ (1.21)	\$ (1.09)
Weighted-average number of shares used in computing net loss per share, basic and diluted	146,795,826	143,385,045	145,685,993	142,376,280

*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				
<b>Balance - December 31, 2022</b>	144,438,304	\$ 144	\$ 1,911,632	\$ (1,235,980)	\$ (9,926)	\$ 665,870
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	—	—	—	(98,704)	—	(98,704)
Net unrealized gain on available-for-sale investments	—	—	—	—	3,992	3,992
<b>Balance - March 31, 2023</b>	145,740,333	146	1,932,734	(1,334,684)	(5,934)	592,262
Issuance of common stock from ATM offering, net of commissions and offering costs of \$1.6 million	20,288,330	20	87,898	—	—	87,918
Issuance of common stock upon exercise of stock options and vesting of RSUs	1,105,001	1	1,605	—	—	1,606
Vesting of early exercised common stock	—	—	432	—	—	432
Stock-based compensation	—	—	16,594	—	—	16,594
Net loss	—	—	—	(77,989)	—	(77,989)
Net unrealized gain on available-for-sale investments	—	—	—	—	2,083	2,083
<b>Balance - June 30, 2023</b>	<u>167,133,664</u>	<u>\$ 167</u>	<u>\$ 2,039,263</u>	<u>\$ (1,412,673)</u>	<u>\$ (3,851)</u>	<u>\$ 622,906</u>

*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 Loss	Total Stockholders' Equity
	Shares	Amount				
<b>Balance - December 31, 2021</b>	142,623,065	\$ 142	\$ 1,822,179	\$ (903,348)	\$ (2,567)	\$ 916,406
Issuance of common stock upon exercise of stock options and vesting of RSUs	715,961	1	282	—	—	283
Vesting of early exercised common stock	—	—	1,228	—	—	1,228
Stock-based compensation	—	—	22,315	—	—	22,315
Employee stock purchase plan	230,876	—	1,530	—	—	1,530
Net loss	—	—	—	(79,850)	—	(79,850)
Net unrealized loss on available-for-sale investments	—	—	—	—	(6,682)	(6,682)
<b>Balance - March 31, 2022</b>	143,569,902	143	1,847,534	(983,198)	(9,249)	855,230
Issuance of common stock upon exercise of stock options and vesting of RSUs	153,269	1	24	—	—	25
Vesting of early exercised common stock	—	—	813	—	—	813
Stock-based compensation	—	—	22,891	—	—	22,891
Net loss	—	—	—	(74,787)	—	(74,787)
Net unrealized loss on available-for-sale investments	—	—	—	—	(2,223)	(2,223)
<b>Balance - June 30, 2022</b>	143,723,171	\$ 144	\$ 1,871,262	\$ (1,057,985)	\$ (11,472)	\$ 801,949

*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)

	<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (176,693)	\$ (154,637)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	35,364	45,206
Depreciation and amortization	7,150	7,367
Net amortization/accretion on investment securities	(566)	2,240
Non-cash rent expense	357	1,640
Share of loss from equity method investment	2,907	2,309
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,365	(8,515)
Other long-term assets	(55)	(2,803)
Accounts payable	(3,233)	917
Accrued and other current liabilities	5,610	(3,334)
Deferred revenue	(656)	413
Other long-term liabilities	(46)	(1,571)
Net cash used in operating activities	<u>(128,496)</u>	<u>(110,768)</u>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment	(1,323)	(3,276)
Proceeds from sales of investments	5,623	—
Proceeds from maturities of investments	296,309	185,797
Purchase of investments	(170,514)	(150,864)
Net cash provided by investing activities	<u>130,095</u>	<u>31,657</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock from ATM offering, net of commissions and issuance costs	87,918	—
Proceeds from issuance of common stock upon exercise of stock options	1,606	308
Proceeds from issuance of common stock under the employee stock purchase plan	1,731	1,530
Net cash provided by financing activities	<u>91,255</u>	<u>1,838</u>
Net change in cash and cash equivalents and restricted cash	92,854	(77,273)
Cash and cash equivalents and restricted cash — beginning of period	72,196	183,606
Cash and cash equivalents and restricted cash — end of period	<u>\$ 165,050</u>	<u>\$ 106,333</u>
<b>Non-cash investing activities:</b>		
Right-of-use asset obtained in exchange for lease liability	\$ —	\$ 31,361
<b>Supplemental disclosure:</b>		
Cash paid for amounts included in the measurement of lease liabilities	\$ (5,989)	\$ (3,983)
Cash received for amounts related to tenant improvement allowances	\$ —	\$ 325

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

**Public Offerings**

In November 2019, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen), as amended on November 2, 2022, under which the Company may from time-to-time issue and sell shares of its common stock through Cowen in at-the-market (ATM) offerings for an aggregate offering price of up to \$250.0 million. The aggregate compensation payable to Cowen as the Company's sales agent equals up to 3.0% of the gross sales price of the shares sold through Cowen pursuant to the sales agreement. During the three months ended June 2023, the Company sold an aggregate of 20,288,330 shares of common stock in ATM offerings resulting in net proceeds of \$87.9 million. As of June 30, 2023, \$77.9 million remains available for sale under the sales agreement with Cowen.

**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 \$544.5 million as of June 30, 2023. Since inception through June 30, 2023, the Company has incurred cumulative net losses of \$1.4 billion. 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. All material intercompany balances and transactions have been eliminated during consolidation.

The condensed consolidated balance sheet as of June 30, 2023, the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2023 and 2022, the condensed consolidated statements of stockholders' equity as of June 30, 2023 and 2022, the condensed consolidated statements of cash flows for the six months ended June 30, 2023 and 2022, 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 and six months ended June 30, 2023 are not necessarily indicative of the results to be expected for the year ending December 31, 2023, 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, 2022, included in the Company's Annual Report on Form 10-K filed with the SEC on February 28, 2023.

### ***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 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 and six months ended June 30, 2023, 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 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 June 30, 2023 and as of December 31, 2022.

Financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of June 30, 2023 and as of December 31, 2022 are presented in the following tables:

	<b>June 30, 2023</b>			
	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>	<b>Fair Value</b>
	<b>(In thousands)</b>			
<b>Financial Assets:</b>				
Money market funds (1)	\$ 148,396	\$ —	\$ —	\$ 148,396
Commercial paper	—	13,990	—	13,990
Corporate bonds	—	98,594	—	98,594
U.S. treasury securities	250,221	—	—	250,221
U.S. agency securities	—	26,985	—	26,985
Total financial assets	<u>\$ 398,617</u>	<u>\$ 139,569</u>	<u>\$ —</u>	<u>\$ 538,186</u>

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

(1) Included within cash and cash equivalents on the Company's 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 June 30, 2023 and as of December 31, 2022 are presented in the following tables:

<b>June 30, 2023</b>				
	<b>Amortized Cost</b>	<b>Unrealized Gains</b>	<b>Unrealized Losses</b>	<b>Fair Value</b>
<b>(In thousands)</b>				
Money market funds	\$ 148,396	\$ —	\$ —	\$ 148,396
Commercial paper	13,992	—	(2)	13,990
Corporate bonds	99,518	—	(924)	98,594
U.S. treasury securities	251,687	14	(1,480)	250,221
U.S. agency securities	28,000	—	(1,015)	26,985
Total cash equivalents and investments	<u>\$ 541,593</u>	<u>\$ 14</u>	<u>\$ (3,421)</u>	<u>\$ 538,186</u>
Classified as:				
Cash equivalents				\$ 148,396
Short-term investments				337,204
Long-term investments				52,586
Total cash equivalents and investments				<u>\$ 538,186</u>

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

As of June 30, 2023, the remaining contractual maturities of available-for-sale securities were less than 2 years. Realized losses on available-for-sale securities for the three and six months ended June 30, 2023 were zero and \$1.0 million, respectively. There were no significant realized losses on available-for-sale securities for the three and six months ended June 30, 2022. As of June 30, 2023, unrealized losses on available-for-sale securities are not attributed to credit risk. The Company believes that it is more likely than not that investments in an unrealized loss position will be held until maturity and all interest and principal will be received. The Company 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 June 30, 2023 and December 31, 2022, securities with a fair value of \$191.8 million and \$329.4 million, respectively, were in a continuous net unrealized loss position for more than 12 months. To date, the Company has not recorded any impairment charges on available-for-sale securities.

As of June 30, 2023 and December 31, 2022, the Company recognized \$1.1 million and \$1.8 million, respectively, of accrued interest receivable from available-for-sale securities within prepaid expenses and other current assets on the consolidated balance sheets.

## 5. Balance Sheet Components

### *Property and Equipment, Net*

Property and Equipment consist of the following:

	June 30, 2023	December 31, 2022
(In thousands)		
Leasehold improvements	\$ 108,593	\$ 108,550
Laboratory equipment	32,926	32,601
Computer equipment and purchased software	4,663	4,533
Furniture and fixtures	4,208	4,012
Construction in progress	31	28
Total	150,421	149,724
Less: accumulated depreciation	(44,035)	(36,885)
Total property and equipment, net	\$ 106,386	\$ 112,839

## 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 and six months ended June 30, 2023 or 2022.

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 Collectis*

As part of the Pfizer Agreement, Pfizer assigned to the Company a Research Collaboration and License Agreement (the Original Collectis Agreement) with Collectis S.A. (Collectis). On March 8, 2019, the Company entered into a License Agreement (the Collectis Agreement) with Collectis. In connection with the execution of the Collectis Agreement, on March 8, 2019, the Company and Collectis also entered into a letter agreement (the Letter Agreement), pursuant to which the Company and Collectis agreed to terminate the Original Collectis Agreement. The Original Collectis 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 Collectis Agreement, Collectis granted to the Company an exclusive, worldwide, royalty-bearing license, on a target-by-target basis, with sublicensing rights under certain conditions, under certain of Collectis'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 Collectis intellectual property rights granted by Collectis to the Company and to Servier pursuant to the Exclusive License and Collaboration

Agreement by and between Servier and Pfizer, dated October 30, 2016, which Pfizer assigned to the Company in April 2018, will survive the termination of the Original Collectis Agreement.

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

The Collectis Agreement provides for development and sales milestone payments by the Company of up to \$185.0 million per product that is directed against an Allogene Target, with aggregate potential development and sales milestone payments totaling up to \$2.8 billion. Collectis is also eligible to receive tiered royalties on annual worldwide net sales of any products that are commercialized by the Company that contain or incorporate, are made using or are claimed or covered by, Collectis intellectual property licensed to the Company under the Collectis Agreement (the Allogene Products), at rates in the high single-digit percentages. Such royalties may be reduced, on a licensed product-by-licensed product and country-by-country basis, for generic entry and for payments due under licenses of third-party patents. Pursuant to the Collectis Agreement, and subject to certain exceptions, the Company is required to indemnify Collectis against all 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 Collectis Agreement, and Collectis is required, subject to certain exceptions, to indemnify the Company against all third party claims related to the development, manufacturing, commercialization or use of CAR T products directed at Collectis Targets or arising out of Collectis's material breach of the representations, warranties or covenants set forth in the Collectis Agreement.

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

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

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

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

All costs the Company incurred in connection with this agreement were recognized as research and development expenses in the condensed consolidated statements of operations. For the three and six months ended June 30, 2023 and 2022, zero costs were incurred related to the achievement of a clinical development milestone under this agreement.

#### ***License and Collaboration Agreement with Servier***

As part of the Pfizer Agreement, Pfizer assigned to the Company an Exclusive License and Collaboration Agreement (the Servier Agreement), with Les Laboratoires Servier SAS and Institut de Recherches Internationales Servier SAS (collectively, Servier) to develop, manufacture and commercialize certain allogeneic anti-CD19 CAR T cell product candidates, including UCART19, in the United States with the option to obtain the rights over additional anti-CD19 product candidates and for allogeneic CAR T cell product candidates directed against one additional target. In October 2019, the Company agreed to waive its rights to the one additional target.

Under the Servier Agreement, the Company has an exclusive license to develop, manufacture and commercialize UCART19, ALLO-501 and ALLO-501A in the field of anti-tumor adoptive immunotherapy in the United States, with an exclusive option to obtain the same rights for additional product candidates in the United States and, if Servier does not elect to pursue development or commercialization of those product candidates in certain markets outside of the United States pursuant to its license, outside of the United States as well. The Company is not required to make any additional payments to Servier to exercise an option. If the Company opts-in to another product candidate, Servier has the right to obtain rights to such product candidate outside the United States and to share development costs for such product candidate.

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

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

The Company is required to make milestone payments to Servier upon successful completion of regulatory and sales milestones. The Servier Agreement provides for aggregate potential payments by the Company to Servier of up to \$137.5 million upon successful completion of various regulatory milestones, and aggregate potential payments by the Company to Servier of up to \$78.0 million upon successful completion of various sales milestones. Similarly, Servier is required to make milestone payments upon successful completion of regulatory and sales milestones for products directed at the Allogene-target covered by the Servier Agreement that achieves such milestones. The total potential payments that Servier is obligated to make to the Company under the Servier Agreement upon successful completion of regulatory and sales milestones are \$42.0 million and €70.5 million (\$76.7 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.

For the three and six months ended June 30, 2023, the Company recorded \$0.5 million and \$0.4 million, respectively, of net cost recoveries under the cost-sharing terms of the Servier Agreement as a reduction to research and development expenses. For the three and six months ended June 30, 2022, the Company recorded \$11.6 million and \$16.7 million, respectively, of net cost recoveries. As of June 30, 2023 and December 31, 2022, amounts due from Servier of zero and \$1.5 million, respectively, were recorded in other current assets in the accompanying condensed consolidated balance sheets.

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

### ***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 June 30, 2023, and continued to account for its investment in Notch as an equity method investment.

Under the Notch Agreement, Notch will be eligible to receive up to \$7.25 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.

For the three and six months ended June 30, 2023, the Company recorded \$0.8 million and \$1.8 million, respectively, in collaboration costs as research and development expenses. For the three and six months ended June 30, 2022, the Company recorded \$0.9 million and \$1.7 million, respectively, in collaboration costs as research and development expenses.

### ***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. 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 and six months ended June 30, 2023, the Company recorded \$0.6 million and \$1.0 million, respectively, in collaboration costs as research and development expenses. For the three and six months ended June 30, 2022, the Company recorded \$0.6 million and \$0.9 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 June 30, 2023, the Company and Overland are the sole equity holders in Allogene Overland. The Company received \$40 million from Allogene Overland as partial consideration for the License Agreement.

Pursuant to the License Agreement, the Company granted Allogene Overland an exclusive license to develop, manufacture and commercialize certain allogeneic CAR T cell candidates directed at four targets, BCMA, CD70, FLT3, and DLL3, in the JV Territory. As consideration, the Company would also be entitled to additional regulatory milestone payments of up to \$40.0 million and, subject to certain conditions, tiered low-to-mid single-digit sales royalties. Subsequent to entering into the License Agreement, Allogene Overland assigned the License Agreement to a wholly-owned subsidiary, Allogene Overland BioPharm (HK) Limited. 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) if and when available 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 payments to be received during the duration of the contract. Fixed consideration exists in the form of the upfront payment. 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 shares of Series Seed Preferred Stock were accounted for as part of the Company's joint venture and equity method accounting upon formation of the joint venture, and as such, were excluded from the transaction price. The Company determined that the initial transaction price consists of the upfront payment of \$40.0 million. 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 transaction price allocated to the license of intellectual property and delivery of know-how will be recognized upon grant of license and delivery of know-how. The transaction price allocated to (i) the manufacturing license, related know-how and support services, (ii) if and when available know-how developed in future periods, and (iii) participation in the joint steering committee, 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 June 30, 2023 and December 31, 2022, respectively. The Company does not have the power to independently 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.

For the three and six months ended June 30, 2023 and 2022, the Company recognized less than \$0.1 million of collaboration revenue. Revenue recognized was due to delivery of the know-how performance obligations. For the three and six months ended June 30, 2023, the Company recorded less than \$0.1 million of net cost recoveries under the terms of the license agreement as a reduction to research and development expenses. For the three and six months ended June 30, 2022, the Company recorded zero and \$0.3 million, respectively, of net cost recoveries under the terms of the license agreement as a reduction to research and development expenses.

#### ***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 January 2022, 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.

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 and six months ended June 30, 2023, the Company recorded \$1.3 million and \$1.8 million, respectively, in research and development expenses related to collaboration costs. For the three and six months ended June 30, 2022, the Company recorded \$0.4 million and \$3.9 million, respectively, in research and development expenses related to the upfront payment and collaboration costs. For the three and six months ended June 30, 2023, \$0.1 million in costs were incurred related to the achievement of a milestone under the Antion Collaboration and License Agreement. For the three and six months ended June 30, 2022, zero costs were incurred related to the achievement of milestone under the Antion Collaboration and License Agreement.

As of June 30, 2023 and December 31, 2022, research and development expenses recorded in accrued and other liabilities were \$1.4 million and \$0.5 million, respectively. As of June 30, 2023 and December 31, 2022, the Company's total equity investment in Antion was \$3.0 million and is recognized in other long-term assets in the condensed consolidated balance sheets.

On July 11, 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 million investment in Antion following the completion of certain milestones, the Company agreed to make a \$2 million investment in Antion's preferred shares and acquired warrants to purchase an additional \$3 million of Antion's preferred shares.

## 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.

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 June 30, 2023 and December 31, 2022.

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

	June 30, 2023	December 31, 2022
Operating lease liabilities		
Current portion included in accrued and other current liabilities	\$ 6,381	\$ 6,002
Long-term portion of lease liabilities	91,821	95,122
Total operating lease liabilities	<u>\$ 98,202</u>	<u>\$ 101,124</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating lease cost	\$ 3,175	\$ 3,177	\$ 6,356	\$ 5,299
Variable lease cost	672	397	1,363	852
Total lease costs	<u>\$ 3,847</u>	<u>\$ 3,574</u>	<u>\$ 7,719</u>	<u>\$ 6,151</u>

Cash paid for amounts included in the measurement of lease liabilities for the six months ended June 30, 2023 was \$6.0 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 June 30, 2023 were as follows:

<b>Year ending December 31:</b>	<b>(In thousands)</b>
2023 (remaining 6 months)	\$ 6,060
2024	12,447
2025	12,627
2026	12,819
2027	13,257
2028 and thereafter	77,235
<b>Total undiscounted lease payments</b>	<b>134,445</b>
Less: Present value adjustment	(36,243)
<b>Total</b>	<b>\$ 98,202</b>

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 6.88%. As of June 30, 2023, the weighted average remaining lease term for our operating leases is 9.50 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 June 30, 2023 and December 31, 2022.

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 June 30, 2023.

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 June 30, 2023, the Company had non-cancellable purchase commitments of \$0.4 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 June 30, 2023 and December 31, 2022 was \$9.9 million and \$12.8 million, respectively, and the Company accounted for the investment using the equity method of accounting. During the three and six months ended June 30, 2023 and 2022, the Company recognized its share of Notch's net loss 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 a Share Purchase Agreement and 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 which had a carrying value of zero. The Company accounts for its investment in Allogene Overland as an equity method investment at carrying value. The Company's total equity investment in Allogene Overland was zero as of June 30, 2023 and December 31, 2022.

The Company's equity investment in Allogene Overland as of June 30, 2023 and December 31, 2022 had a zero carryover basis. Therefore, the Company did not account for its share of losses incurred by Allogene Overland. See Note 6 for further details.

## **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 June 30, 2023, there were 6,377,914 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:

	<b>Outstanding Options</b>			
	<b>Number of Options</b>	<b>Weighted-Average Exercise Price</b>	<b>Weighted-Average Remaining Contract Term (in years)</b>	<b>Aggregate Intrinsic Value (in thousands)</b>
Balance, December 31, 2022	17,569,575	\$ 12.90	7.73	\$ 6,658
Granted	8,103,938	5.28		
Exercised	(712,931)	2.27		2,226
Forfeited	(3,016,808)	11.55		
Balance, June 30, 2023	<u>21,943,774</u>	\$ 10.62	7.86	\$ 2,142
Exercisable, June 30, 2023	<u>13,354,883</u>	\$ 12.35	7.14	\$ 2,135
Vested and expected to vest, June 30, 2023	<u>21,943,774</u>	\$ 10.62	7.86	\$ 2,142

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 June 30, 2023. For the six months ended June 30, 2023, the estimated weighted-average grant-date fair value of employee options granted was \$3.55 per share. As of June 30, 2023, there was \$77.2 million of unrecognized stock-based compensation related to unvested stock options, which is expected to be recognized over a weighted-average period of 2 years, 248 days.

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:

	<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
Expected term in years	5.27 - 6.08	5.27 - 6.08
Expected volatility	73.37% - 73.85%	70.82% - 72.57%
Expected risk-free interest rate	3.45% - 4.10%	1.61% - 3.49%
Expected dividend	0%	0%

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

*Expected term*— The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.

*Expected volatility*— The Company uses an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company does not have sufficient trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

*Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.

*Expected dividend*—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

*Expected exercise barrier* - The modified options are assumed to be exercised upon vesting and when the ratio of stock market price to exercise price reaches 2.57, or expiration, whichever is earlier.

### Restricted Stock Unit Activity

The following summarizes restricted stock unit activity under the 2018 Plan:

	Outstanding Restricted Stock Units			
	Restricted Stock Units	Weighted-Average Grant Date Fair Value per Share	Weighted Average Remaining Vesting Life (in years)	Aggregate Intrinsic Value (in thousands)
Unvested December 31, 2022	5,493,406	\$ 16.86	1.54	\$ 34,554
Granted	10,591,009	4.73	2.55	
Vested	(1,349,143)	17.70		
Forfeited	(1,901,277)	10.30		
Unvested June 30, 2023	<u>12,833,995</u>	\$ 7.74	2.34	\$ 63,785
Vested and expected to vest, June 30, 2023	<u>12,833,995</u>	\$ 7.74	2.34	\$ 63,785

As of June 30, 2023, there was \$71.9 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 years, 223 days.

For the six months ended June 2023, the Company granted 3,015,272 performance-based restricted stock units and 1,939,646 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 June 30, 2023, the Company believes that the achievement of the requisite performance conditions for these awards are not probable. As a result, no compensation expense has been recognized related to the performance-based restricted stock units in the quarter ended June 30, 2023. The Company recognized \$0.9 million in stock-based compensation expense related to the restricted units with a market condition for the six months ended June 30, 2023.

Total stock-based compensation expense related to stock options, restricted stock units, employee stock purchase plan and vesting of the founders' common stock was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Research and development	\$ 6,919	\$ 12,972	\$ 16,116	\$ 24,052
General and administrative	9,675	9,919	19,248	21,154
Total stock-based compensation	<u>\$ 16,594</u>	<u>\$ 22,891</u>	<u>\$ 35,364</u>	<u>\$ 45,206</u>

### Early Exercised Options

The Company allows certain of its employees and its directors to exercise options granted under the Prior 2018 Plan and the 2018 Plan prior to vesting. The shares related to early exercised stock options are subject to the Company's lapsing repurchase right upon termination of employment or service on the Company's Board of Directors at the lesser of the original purchase price or fair market value at the time of repurchase. In order to vest, the holders are required to provide continued service to the Company. The proceeds are initially recorded in accrued and other liabilities for the current portion, and other long-term liabilities for the non-current portion. The proceeds are reclassified to paid-in capital as the repurchase right lapses. In May 2021, 293,594 options were early exercised, resulting in proceeds of \$5.3 million. As of June 30, 2023 and December 31, 2022, there was \$1.5 million and \$1.9 million, respectively, recorded in accrued and other liabilities and zero and \$0.6 million, respectively, recorded in other long-term liabilities related to shares held by employees and directors that were subject to repurchase. The underlying shares are shown as outstanding in the condensed consolidated financial statements but the shares which are subject to future vesting conditions are not included in the calculation of earnings per share.

## 10. Related Party Transactions

### *Collaboration Revenue*

In December 2020, the Company entered into a 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 BioPharm (HK) Limited. On April 1, 2022, Allogene Overland HK assigned the license agreement to Allogene Overland Biopharm (PRC) Co., Limited. For the three and six months ended June 30, 2023 and 2022, the Company recognized less than \$0.1 million of collaboration revenue under this agreement.

For the three and six months ended June 30, 2023, the Company recorded less than \$0.1 million of net cost recoveries under the terms of the license agreement as a reduction to research and development expenses. For the three and six months ended June 30, 2022, the Company recorded zero and \$0.3 million, respectively, of net cost recoveries under the terms of the license agreement as a reduction to research and development expenses.

### *Sublease Agreement*

In December 2018, the Company entered into a sublease with Bellco Capital LLC (Bellco) for 1,293 square feet of office space in Los Angeles, California for a three year term. On April 1, 2020, Bellco Capital Advisors Inc. assumed all rights, title, interests and obligations under the sublease from Bellco Capital LLC. In November 2021, the sublease was extended to June 30, 2025. The sublease was amended, effective in July 2022, to move to a nearby location, with office space of 737 square feet. The Company's executive chairman, Arie Beldegrun, M.D., FACS, is a trustee of the Beldegrun Family Trust, which controls Bellco Capital Advisors Inc. The total right of use asset and associated liability recorded related to this related party lease was \$0.1 million and \$0.2 million at June 30, 2023 and December 31, 2022, respectively.

In February 2023, the Company subleased an additional 2,030 square feet of office space in Los Angeles, California, from Bellco. The sublease term is 115 months, subject to certain early termination rights. The sublease is expected to commence January 1, 2024. The Company paid approximately \$0.2 million towards the monthly base rent due for the first month of the sublease term and its share of the security deposit. The total estimated amount of base rent is \$2.9 million, subject to rent abatement. The Company also expects to contribute to certain tenant improvements to the space totaling to its share of the total tenant contribution.

### *Consulting Agreements*

In June 2018, the Company entered into a services agreement with Two River Consulting, LLC (Two River), a firm affiliated with the Company's President and Chief Executive Officer, the Company's Executive Chair of the board of directors, and a director of the Company to provide various managerial, clinical development, administrative, accounting and financial services to the Company. The costs incurred for services provided under this agreement were \$0.1 million and \$0.2 million for the three and six months ended June 30, 2023, respectively. The costs incurred for services provided under this agreement were \$0.3 million and \$0.5 million for the three and six months ended June 30, 2022, respectively.

In August 2018, the Company entered into a consulting agreement with Bellco. Pursuant to the consulting agreement, Bellco provides certain services for the Company, which are performed by Dr. Beldegrun, the Company's executive chair, and include without limitation, providing advice and analysis with respect to the Company's business, business strategy and potential opportunities in the field of allogeneic CAR T cell therapy and any other aspect of the CAR T cell therapy business as the Company may agree. In consideration for these services, the Company paid Bellco \$40,217 per month in arrears commencing January 2022. The Company may also, at its discretion, pay Bellco an annual performance award in an amount up to 60% of the aggregate compensation payable to Bellco in a calendar year. The Company also reimburses Bellco for out-of-pocket expenses incurred in performing the services. The costs incurred for services provided, bonus, and out-of-pocket expenses incurred under this consulting agreement were \$0.2 million and \$0.4 million for the three and six months ended June 30, 2023, respectively. The costs incurred for services provided and out-of-pocket expenses incurred under this consulting agreement were \$0.2 million and \$0.4 million for the three and six months ended June 30, 2022, respectively.

## 11. Income Taxes

The Company has a history of losses and expects to record a loss in 2023. 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:

	June 30,	
	2023	2022
Stock options to purchase common stock	21,943,774	18,248,432
Restricted stock units subject to vesting	12,833,995	6,186,433
Expected shares to be purchased under Employee Stock Purchase Plan	1,749,295	1,300,989
Early exercised stock options subject to future vesting	82,051	186,224
Total	36,609,115	25,922,078

**13. Subsequent Events**

None.

**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 and the audited financial statements and notes thereto as of and for the year ended December 31, 2022 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, 2022 (Annual Report), which was filed with the Securities and Exchange Commission (SEC) on February 28, 2023. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q 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 on Form 10-Q, 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. We are developing a pipeline of off-the-shelf T cell product candidates that are designed to target and kill cancer cells. Our engineered T cells are allogeneic, meaning they are derived from healthy donors for intended use in any patient, rather than from an individual patient for that patient’s use, as in the case of autologous T cells. We believe this key difference will enable us to deliver readily available treatments faster, more reliably, at greater scale, and to more patients.

We have a deep pipeline of allogeneic chimeric antigen receptor (CAR) T cell product candidates targeting multiple promising antigens in a host of hematological malignancies and solid tumors. Pursuant to our Exclusive Collaboration and License Agreement with Servier (Servier Agreement), we have exclusive rights to ALLO-501 and ALLO-501A, CAR T cell



product candidates targeting CD19, in the United States. ALLO-501 and ALLO-501A use Collectis S.A. (Collectis) technologies under which Servier holds an exclusive worldwide license from Collectis.

We are conducting long-term follow-up in our Phase 1 clinical trial (the ALPHA trial) of ALLO-501 in patients with relapsed or refractory (R/R) non-Hodgkin lymphoma (NHL). We are also progressing the development of the second-generation version of ALLO-501, known as ALLO-501A. We have removed rituximab recognition domains in ALLO-501A, which we believe will potentially facilitate treatment of more patients, as rituximab is a typical part of a treatment regimen for a patient with NHL.

In the fourth quarter of 2022, we initiated a Phase 2 clinical trial for ALLO-501A (the ALPHA2 trial) in R/R large B cell lymphoma (LBCL). The single-arm ALPHA2 trial will utilize a single dose of ALLO-501A at 120 million CAR+ cells with a lymphodepletion regimen comprised of fludarabine (30 mg/m<sup>2</sup>/day x 3 days) and cyclophosphamide (300 mg/m<sup>2</sup>/day x 3 days) plus ALLO-647 (90 mg). We plan to enroll approximately 100 patients who have received at least two prior lines of therapy and have not received any prior anti-CD19 therapy, including CAR T therapy. The primary endpoint is objective response rate (ORR) and the key secondary endpoint is duration of response (DoR).

We recently initiated the EXPAND trial, which is expected to enroll approximately 70 patients with R/R LBCL and is intended to demonstrate the overall contribution of ALLO-647 to the benefit to risk ratio of the lymphodepletion regimen for ALLO-501A. Patients will be randomized to receive the same single 120 million CAR+ cell dose of ALLO-501A as in the ALPHA2 trial and either lymphodepletion with fludarabine and cyclophosphamide (control arm) or the lymphodepletion regimen of the ALPHA2 trial (active arm). The primary endpoint of this trial is progression free survival, and the key secondary endpoints are ORR, DoR, and the safety of ALLO-647. Assuming favorable outcomes and subject to FDA discussions, we plan to seek FDA approval of ALLO-501A and ALLO-647 on the basis of the ALPHA2 trial and the EXPAND companion trial.

We are sponsoring two clinical trials in adult patients with R/R multiple myeloma, a Phase 1 clinical trial (the UNIVERSAL trial) of ALLO-715 and a Phase 1 clinical trial (the IGNITE trial) of ALLO-605, our first product candidate to incorporate our TurboCAR technology. TurboCAR technology allows cytokine signaling to be engineered selectively into CAR T cells and has shown the ability to improve the potency and persistence of the cells and to delay exhaustion of the cells in preclinical models. We are currently reviewing and optimizing the manufacturing process for our BCMA program and are not enrolling patients in the UNIVERSAL and IGNITE trials at this time.

We also continue to advance the Phase 1 clinical trial (the TRAVERSE trial) of ALLO-316, an allogeneic CAR T cell product candidate targeting CD70, in adult patients with advanced or metastatic clear cell renal cell carcinoma (ccRCC). Subject to ongoing results in the TRAVERSE trial, we intend to complete planned dose exploration and initiate expansion cohort enrollment in 2023.

Since inception, we have had significant operating losses. Our net losses were \$78.0 million and \$176.7 million for the three and six months ended June 30, 2023, respectively. As of June 30, 2023, we had an accumulated deficit of \$1.4 billion. As of June 30, 2023, we had \$544.5 million in cash and cash equivalents and investments and we expect our cash runway to fund operations into 2H 2025. 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.

## Recent Developments

On June 15, 2023, we presented updated data at the International Conference on Malignant Lymphoma (ICML) from the Phase 1 ALPHA/ALPHA2 trials of ALLO-501/501A in 33 CAR T naïve patients with relapsed/refractory (r/r) large B-cell lymphoma (LBCL) treated with the Alloy manufacturing process material across different CAR T dosing and lymphodepletion regimens. Earlier in June, data from the 12 patients, a subset of these 33 CAR T naïve patients, who received regimen being utilized in ongoing Phase 2 trials was presented at American Society of Clinical Oncology (ASCO) Annual Meeting.

The updated analysis (data cutoff April 20, 2023) of ALPHA/ALPHA2 examined data from all 33 CAR T-naïve patients with r/r LBCL who were treated with a single infusion or consolidation therapy (two planned infusions) of ALLO-501/501A manufactured using the Alloy manufacturing process. Patients received lymphodepletion with fludarabine (30 mg/m<sup>2</sup>/day x 3 days) and cyclophosphamide (300 mg/m<sup>2</sup>/day x 3 days) and varying doses of ALLO-647 (from 13 mg/day to 30 mg/day x 3 days).

The median time from enrollment to the start of therapy was three days and 100% of patients received product per specifications. No patients received bridging therapy. The dosing breakdown for the 33 patients included in this data set is as follows:

- 12 patients treated with a single dose of ALLO-501/501A and FCA90 lymphodepletion (Phase 2 regimen; recap of the ASCO 2023 data presentation)
- 6 patients treated with a single dose of ALLO-501/501A and FCA<90 lymphodepletion
- 15 patients treated with consolidation dosing of ALLO-501/501A and split lymphodepletion

	CAR T- Naïve Patients with r/r LBCL Alloy Manufacturing Process			
	All (N=33)	Phase 2 Regimen (N=12)	FCA<90 (N=6)	Consolidation Dosing (N=15)
Overall Response Rate (ORR), n (%)	19 (58)	8 (67)	3 (50)	8 (53)
Complete Response Rate (CR), n (%)	14 (42)	7 (58)	1 (17)	6 (40)
6 Month Complete Response, n (%)	10 (30)	5 (42)	0	5 (33)

Seven of 12 (58%) patients receiving the Phase 2 regimen achieved a CR and five (42%) maintained a CR through Month 6. Of the five patients who were in CR at 6 months, four (80%) remained in CR. The fifth patient had disease progression at 24 months. The median duration of response was 23.1 months with three patients remaining in remission for over 24 months and the longest remaining in remission for over 31 months. Across all 33 patients the CR rate was 42% with 30% maintaining a CR at Month 6. These results indicating complete responses are more common with lymphodepletion regimens containing 90 mg of ALLO-647 (FCA90). Median duration of response for both the overall population (n=33) and the patients treated with the Phase 2 regimen (n=12) was 23.1 months.

	CAR T- Naïve Patients with r/r LBCL							
	All (N=33)		Phase 2 Regimen (N=12)		FCA<90 (N=6)		Consolidation (N=15)	
	All Gr N (%)	Gr 3+ N (%)	All Gr N (%)	Gr 3+ N (%)	All Gr N (%)	Gr 3+ N (%)	All Gr N (%)	Gr 3+ N (%)
CRS	8 (24)	0	4 (33)	0	1 (17)	0	3 (20)	0
Neurotoxicity	13 (39)	2 (6)	4 (33)	0	2 (33)	0	7 (47)	2 (13)
ICANS	0	0	0	0	0	0	0	0
GvHD	0	0	0	0	0	0	0	0
IRR	16 (49)	3 (9)	8 (67)	0	3 (50)	1 (17)	5 (33)	2 (13)
Infection	19 (58)	5 (15)	8 (67)	1 (8)	3 (50)	1 (17)	8 (53)	3 (20)
Prolonged Gr3+ Cytopenia	—	4 (12)	—	2 (17)	—	0	—	2 (13)

Across the 33 patients, treatment was generally well tolerated with no incidences of Grade 3 or greater cytokine release syndrome, and no cases of immune effector cell-associated neurotoxicity syndrome or graft versus host disease. Cytopenia and infections were manageable and comparable to the experience with autologous CAR T cell therapies in patients with r/r LBCL.

The ALPHA/ALPHA2 Phase 1 trials were designed to assess the safety, tolerability, and preliminary efficacy at increasing dose levels of ALLO-501 and ALLO-501A, allogeneic CAR T cell product candidates that target CD19. In addition to exploring multiple cell doses, these studies evaluated various doses of ALLO-647, our proprietary lymphodepleting antibody is designed to prevent premature rejection of AlloCAR T cells. We are currently enrolling the potentially pivotal Phase 2 ALPHA2 trial of ALLO-501A in LBCL and expect to complete enrollment in the first half of 2024 with the first data readout planned by the end of 2024. We are currently enrolling in Canada and expect enrollment in Europe to begin in the third quarter of 2023 and in Australia by year-end.

In addition, we are conducting EXPAND, a trial in which patients with LBCL are randomized to receive a lymphodepletion regimen comprised of fludarabine and cyclophosphamide with or without ALLO-647. EXPAND is currently open to enrollment in the US and is expected to be open in additional regions in 2023.

## **Our Research and Development and License Agreements**

### ***Asset Contribution Agreement with Pfizer***

In April 2018, we entered into an Asset Contribution Agreement (Pfizer Agreement) with Pfizer pursuant to which we acquired certain assets and assumed certain liabilities from Pfizer, including agreements with 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 and Collaboration Agreement with Servier***

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

On September 15, 2022, Servier sent a notice of discontinuation (Discontinuation) of its involvement in the development of all licensed products directed against CD19, including UCART19, ALLO-501 and ALLO-501A (collectively, CD19 Products), pursuant to the Servier Agreement. Servier's Discontinuation provides us with the right to elect a license to the CD19 Products outside of the United States (Ex-US Option) and does not otherwise affect our current exclusive license for the development and commercialization of CD19 Products in the United States. Upon any exercise of the Ex-US Option by us, our potential milestone payments with respect to ALLO-501A would increase for any first dosing in Phase 2, first dosing in Phase 3 and regulatory approval by €46 million in the aggregate. In addition, upon any such exercise of the Ex-US Option, Servier's obligation to reimburse us for 40% of the development costs for CD19 Products would cease. However, Servier has disputed the implications of the Discontinuation, namely whether development cost contributions continue and the timeframe during which we have the right to elect a license to CD19 Products outside of the United States. Moreover, in December 2022, Servier sent us a notice for material breach due to our purported refusal to allow an audit of certain manufacturing costs under our cost share arrangement. While we do not believe Servier has such an audit right, we submitted to a review of our manufacturing costs of CD19 Products to recover outstanding manufacturing costs owed by Servier to us. In July 2023, Servier sent us a second notice for material breach alleging that we overcharged Servier based on Servier and its accounting firm's review of costs eligible for cost-sharing under the Servier Agreement. We disagree with the material breach allegations and we are disputing such allegations. For more information, see "Risk Factors—Servier's Discontinuation of its involvement in the development of CD19 Products and our disputes with Servier may have adverse consequences."

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

### ***Collaboration and License Agreement with Notch***

On November 1, 2019, we entered into a Collaboration and License Agreement (the Notch Agreement) with Notch Therapeutics Inc. (Notch), pursuant to which Notch granted us an exclusive, worldwide, royalty-bearing, sublicensable license under certain of Notch's intellectual property to develop, make, use, sell, import, and otherwise commercialize therapeutic gene-edited T cell and/or natural killer cell products from induced pluripotent stem cells directed at certain CAR targets for initial application in NHL, B-cell precursor acute lymphoblastic leukemia (ALL) and multiple myeloma. In addition, Notch has granted us an option to add certain specified targets to our exclusive license in exchange for an agreed upon per-target option fee.

The Notch Agreement includes a research collaboration to conduct research and pre-clinical development activities to generate engineered cells directed to our exclusive targets, which will be conducted in accordance with an agreed research plan and budget under the oversight of a joint development committee. In connection with the execution of the Notch Agreement,

we made an upfront payment to Notch of \$10.0 million. In addition, we made a \$5.0 million investment in Notch's series seed convertible preferred stock, resulting in us having a 25% ownership interest in Notch's outstanding capital stock on a fully diluted basis immediately following the investment. In February 2021, we made an additional \$15.9 million investment in Notch's Series A preferred stock. In October 2021, we made an additional \$1.8 million investment in Notch's common stock. Immediately following this transaction, our share in Notch was 23.0% on a voting interest basis. See Note 6 to our 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 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), 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.

### **Components of Results of Operations**

#### ***Revenues***

As of June 30, 2023, our revenue has been exclusively generated from our collaboration and 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 Allogene Overland Biopharm (PRC) Co., Limited agreement.

In the future, we may generate revenue from a combination of product sales, government or other third-party funding, 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 and six months ended June 30, 2023 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 ALLO-501A.

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.

#### ***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 Income (Expenses)***

Other income (expenses) consists of non-operating income and expenses, including primarily our share of equity investments' net losses for the period.

#### **Results of Operations**

##### ***Comparison of the Three Months Ended June 30, 2023 and 2022***

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

	Three Months Ended June 30,		Change	
	2023	2022	\$	%
Collaboration revenue - related party	\$ 44	\$ 86	\$ (42)	(49)%
Operating expenses:				
Research and development	62,038	57,171	4,867	9 %
General and administrative	18,524	19,509	(985)	(5)%
Total operating expenses	80,562	76,680	3,882	5 %
Loss from operations	(80,518)	(76,594)	(3,924)	5 %
Other income (expense), net:				
Interest and other income, net	3,778	315	3,463	*
Other (expenses) income	(1,249)	1,492	(2,741)	*
Total other income, net	2,529	1,807	722	40 %
Net Loss	\$ (77,989)	\$ (74,787)	\$ (3,202)	4 %

\* Change in excess of 100%

#### ***Collaboration revenue - related party***

Collaboration revenue was less than \$0.1 million for the three months ended June 30, 2023 and 2022. Revenue recognized in the three months ended June 30, 2023 and 2022 was due to the delivery of the know-how performance obligations related to the License Agreement entered into with Allogene Overland on December 14, 2020.

#### ***Research and Development Expenses***

Research and development expenses were \$62.0 million and \$57.2 million for the three months ended June 30, 2023 and 2022, respectively. The increase of \$4.9 million was driven primarily by a decrease in Servier cost recoveries of \$11.0 million, offset by a decrease in personnel related costs of \$5.2 million and a decrease in external costs relating to the advancement of our product candidates due to the timing of development activities and manufacturing runs of \$0.9 million.

#### ***General and Administrative Expenses***

General and administrative expenses were \$18.5 million and \$19.5 million for the three months ended June 30, 2023 and 2022, respectively. The decrease of \$1.0 million was primarily due to a decrease in personnel related costs of \$0.6 million and a decrease in expenses related to outside services of \$0.3 million.

#### ***Interest and Other Income, Net***

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

#### ***Comparison of the Six Months Ended June 30, 2023 and 2022***

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

	Six Months Ended June 30,		Change	
	2023	2022	\$	%
Collaboration revenue - related party	\$ 96	\$ 147	\$ (51)	(35)%
Operating expenses:				
Research and development	142,276	117,327	24,949	21 %
General and administrative	37,408	39,406	(1,998)	(5)%
Total operating expenses	<u>179,684</u>	<u>156,733</u>	<u>22,951</u>	<u>15 %</u>
Loss from operations	(179,588)	(156,586)	(23,002)	15 %
Other income (expense), net:				
Interest and other income, net	5,837	807	5,030	*
Other (expenses) income	(2,942)	1,142	(4,084)	*
Total other income, net	<u>2,895</u>	<u>1,949</u>	<u>946</u>	<u>49 %</u>
Net Loss	<u>\$ (176,693)</u>	<u>\$ (154,637)</u>	<u>\$ (22,056)</u>	<u>14 %</u>

\* Change in excess of 100%

### ***Collaboration revenue - related party***

Collaboration revenue was \$0.1 million for the six months ended June 30, 2023 and 2022. Revenue recognized in the six months ended June 30, 2023 and 2022 was due to the delivery of the know-how performance obligations related to the License Agreement entered into with Allogene Overland on December 14, 2020.

### ***Research and Development Expenses***

Research and development expenses were \$142.3 million and \$117.3 million for the six months ended June 30, 2023 and 2022, respectively. The increase of \$24.9 million was driven primarily by a decrease in Servier cost recoveries of \$16.1 million and an increase in external costs relating to the advancement of our product candidates due to the timing of development activities and manufacturing runs of \$11.0 million, offset by a decrease in personnel related costs of \$4.4 million.

### ***General and Administrative Expenses***

General and administrative expenses were \$37.4 million and \$39.4 million for the six months ended June 30, 2023 and 2022, respectively. The decrease of \$2.0 million was primarily due to a decrease in personnel related costs of \$1.3 million and a decrease in expenses related to outside services of \$0.7 million.

### ***Interest and Other Income, Net***

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

### **Liquidity and Capital Resources**

To date, we have incurred significant net losses and negative cash flows from operations. As of June 30, 2023, we had \$544.5 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 the next 12 months from the date this Quarterly Report on Form 10-Q 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 connection with our IPO in 2018, we sold an aggregate of 20,700,000 shares of our common stock (inclusive of 2,700,000 shares of common stock pursuant to the over-allotment option granted to the



underwriters) at a price of \$18.00 per share and received approximately \$343.3 million in net proceeds. In November 2019, we entered into a sales agreement with Cowen and Company, LLC (Cowen), as amended on November 2, 2022, under which we may from time to time issue and sell shares of our common stock through Cowen in ATM offerings for an aggregate offering price of up to \$250.0 million. During the year ended December 31, 2019, we sold an aggregate of 1,965,082 shares of common stock in ATM offerings resulting in net proceeds of \$54.2 million. During the year ended December 31, 2020, we sold an aggregate of 848,663 shares of common stock in ATM offerings resulting in net proceeds of \$26.2 million. In June 2023, we sold an aggregate of 20,288,330 shares of common stock in ATM offerings resulting in net proceeds of \$87.9 million. As of June 30, 2023, \$77.9 million remains available for sale under the sales agreement with Cowen.

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

### **Cash Flows**

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

	<b>Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
	<b>(In thousands)</b>	
Net cash (used in) provided by:		
Operating activities	\$ (128,496)	\$ (110,768)
Investing activities	130,095	31,657
Financing activities	91,255	1,838
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 92,854</u>	<u>\$ (77,273)</u>

### **Operating Activities**

During the six months ended June 30, 2023, cash used in operating activities of \$128.5 million was attributable to a net loss of \$176.7 million, partially offset by non-cash charges of \$45.2 million and an increase of \$3.0 million in our net operating assets and liabilities. The non-cash charges consisted primarily of stock-based compensation expense of \$35.4 million, depreciation of \$7.2 million, our share of equity investments' net losses for the period of \$2.9 million, net amortization and accretion on investment securities of \$0.6 million, and non-cash rent expense of \$0.4 million. The change in operating assets and liabilities was primarily due to a \$5.6 million increase in accrued and other current liabilities and a \$1.4 million decrease in prepaid expenses and other current assets, offset by a \$3.2 million decrease in accounts payable and a \$0.7 million decrease in deferred revenue.

During the six months ended June 30, 2022, cash used in operating activities of \$110.8 million was attributable to a net loss of \$154.6 million, partially offset by non-cash charges of \$58.8 million and an increase of \$14.9 million in our net operating assets and liabilities. The non-cash charges consisted primarily of stock-based compensation expense of \$45.2 million, depreciation of \$7.4 million, our share of equity investments' net losses for the period of \$2.3 million, net amortization and accretion on investment securities of \$2.2 million, and non-cash rent expense of \$1.6 million. The change in operating assets and liabilities was primarily due to a \$8.5 million increase in prepaid expenses and other current assets, a \$3.3 million decrease in accrued and other current liabilities, a \$2.8 million increase in other long-term assets, and a \$1.6 million decrease in other long-term liabilities, offset by a \$0.9 million increase in accounts payable and a \$0.4 million increase in deferred revenue.

### **Investing Activities**

During the six months ended June 30, 2023, net cash provided by investing activities of \$130.1 million was related to cash provided by investment maturities of \$296.3 million and cash provided by investment sales of \$5.6 million, offset by cash used in purchases of investments of \$170.5 million and cash used in the purchase of property and equipment of \$1.3 million.

During the six months ended June 30, 2022, net cash provided by investing activities of \$31.7 million was related to cash provided by investment maturities of \$185.8 million, offset by cash used in purchases of investments of \$150.9 million and cash used in the purchase of property and equipment of \$3.3 million.

### ***Financing Activities***

During the six months ended June 30, 2023, cash provided by financing activities of \$91.3 million was related to \$87.9 million in net proceeds from the issuance of common stock through ATM transactions, \$1.7 million of cash provided by the sale of common stock through our employee stock purchase plan, and \$1.6 million of cash provided by the issuance of common stock upon exercise of stock options.

During the six months ended June 30, 2022, cash provided by financing activities of \$1.8 million was related to \$1.5 million of cash provided by the sale of common stock through our employee stock purchase plan and \$0.3 million of cash provided by the issuance of common stock upon exercise of stock options.

### **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 June 30, 2023, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales. For additional information regarding our agreements, see Note 6 to our 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 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 June 30, 2023, we had non-cancellable purchase commitments of \$0.4 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. 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 and stock-based compensation 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 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 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 \$544.5 million as of June 30, 2023 consist of bank deposits, money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. A 10% change in the interest rates in effect on June 30, 2023 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 June 30, 2023, we had no receivables denominated in foreign currency.

#### **Item 4. Controls and Procedures.**

##### **Evaluation of Disclosure Controls and Procedures**

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

##### **Changes in Internal Control over Financial Reporting**

We are in the process of implementing new enterprise resource planning software, SAP, as part of a plan to integrate and upgrade our systems and processes. The implementation of this software is scheduled to continue in phases over a number of years. During the first quarter of 2021, we migrated certain areas of our business to SAP, including financial reporting, asset management, procurement, clinical inventory and warehouse management. As the phased implementation of future modules occurs, we expect to experience certain changes to our processes and procedures which, in turn, result in changes to our internal control over financial reporting. While we expect SAP to strengthen our internal financial controls by automating certain manual processes and standardizing business processes and reporting, management will continue to evaluate and monitor our internal controls as processes and procedures in each of the affected areas evolve.

Other than as discussed above, 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 June 30, 2023 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 on Form 10-Q and our other filings with the Securities and Exchange Commission (SEC) before making investment decisions regarding our common stock.*

- We have incurred net losses in every period since our inception and anticipate that we will incur substantial net losses in the future.
- 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 product candidates.
- Servier's discontinuation of its involvement in the development of CD19 products and our disputes with Servier may have adverse consequences.
- Our product candidates are based on novel technologies, which makes it difficult to predict the time and cost of product candidate development and 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 become available.
- 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, 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.
- 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 rely and will continue to rely on third parties to conduct our clinical trials and manufacture our product candidates and critical raw materials. 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 and other specialty raw materials to manufacture our product candidates, and if we do not obtain an adequate supply of T cells from qualified donors or other raw materials, development of those product candidates would be adversely impacted.
- The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our CAR T cell product candidates.
- 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.

## 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 that did not appear as separate risk factors in, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2022 (Annual Report), which was filed with the SEC on February 28, 2023.*

### Risks Related to Our Business and Industry

***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. As a result, we are not profitable and have incurred net losses in each period since our inception. For the year ended December 31, 2022, we reported a net loss of \$332.6 million. For the six months ended June 30, 2023, we reported a net loss of \$176.7 million. As of June 30, 2023, we had an accumulated deficit of \$1.4 billion.

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

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

***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 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 cytokine release syndrome (CRS), neurotoxicity, graft-versus-host disease (GvHD), prolonged cytopenia, aplastic anemia and neutropenic sepsis;
- using medicines to preempt or manage adverse side effects of our product candidates and such medicines may be difficult to source or costly or may not adequately control the side effects and/or may have other safety risks or a detrimental impact on the efficacy of the treatment;
- conditioning patients with chemotherapy and ALLO-647 or other lymphodepletion agents in advance of administering our product candidates, which may be difficult to source, costly or increase the risk of infections and other adverse side effects;
- obtaining regulatory approval, as the FDA and other regulatory authorities have limited experience with development of allogeneic T cell therapies for cancer; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

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

Collectis's TALEN technology involves a relatively new approach 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. Although Collectis has generated nucleases for many specific gene sequences, it has not created nucleases for all gene sequences that we may seek to target, and Collectis may not agree to or have difficulty creating nucleases for other gene sequences that we may seek to target, which could limit the usefulness of this technology. This technology may also not be shown to be effective in clinical studies that Collectis, we or other licensees of Collectis technology 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. 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 for access to TALEN gene editing technology for the manufacturing and development of our 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. We use Collectis's TALEN gene-editing technology

to inactivate a gene coding for TCR $\alpha$ , 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 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 product candidates, we believe we have the potential to reduce the likelihood of a patient's immune system from rejecting the engineered allogeneic T cells for a sufficient period of time to enable a window of persistence during which the engineered allogeneic T cells can actively target and destroy the cancer cells. However, the antibody may not have the benefits that we anticipate and could have adverse effects.

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

***Servier's Discontinuation of its involvement in the development of CD19 Products and our disputes with Servier may have adverse consequences.\****

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

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

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

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

We have concentrated our research, development and manufacturing efforts on our engineered allogeneic T cell therapy and our future success depends on the successful development of this therapeutic approach. We are in the early stages of developing our platform and we have experienced significant development challenges, such as with the prior clinical hold by the FDA, and there can be no assurance that any development problems we have now or experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial facilities or partners, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all. For instance, it will take additional time and expense to transfer any product manufacturing to CF1 and



optimize manufacturing for our BCMA program, each of 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. In addition, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors.

We are also advancing product candidates against unexplored targets and with new technology. For example, we are advancing ALLO-316 against a target, CD70, that has not been validated by any autologous CAR T therapies. 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 or may deplete host T or other immune cells increasing the risk of prolonged blood cell count suppression (cytopenia), inflammatory conditions such as immune effector cell hemophagocytic lymphohistiocytosis-like syndrome (IEC-HS) or infections.

The clinical study requirements of the FDA, European Medicines Agency (EMA) and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. We face additional challenges in obtaining regulatory approval for ALLO-647, which we use as part of our lymphodepletion regimen, and for which we would seek to obtain approval concurrently with approval of a CAR T cell product candidate. Approvals by the EMA and FDA for existing autologous CAR T therapies, such as Kymriah and Yescarta, may not be indicative of what these regulators may require for approval of our therapies. Also, while we expect reduced variability in our products candidates compared to autologous products, we do not have significant clinical data supporting any benefit of lower variability and the use of healthy donor material may create separate variability challenges for us.

More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new product candidates. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the autologous CAR T therapies that have previously been approved. For instance, allogeneic product candidates may result in GvHD or chromosomal abnormalities not experienced with autologous products. Additionally, any Phase 2 trial results, such as in the ALPHA2 trial, may not be representative of Phase 1 results, which were based on limited patients. 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 ALLO-501A, ALLO-316 and our BCMA program candidates are among the first allogeneic products to be evaluated in the clinic, the failure of any such product candidates, or the failure of other allogeneic T cell therapies, including for reasons due to safety, efficacy or durability, may impede our ability to develop our product candidates, and significantly influence physicians' and regulators' opinions in regard to the viability of our entire pipeline of allogeneic T cell therapies. For instance, all of our clinical trials were previously put on clinical hold due to an observation in the ALPHA2 trial. While the clinical hold has been resolved, we could be subject to a clinical hold in the future due to unexpected observations, adverse patient outcomes or other issues.

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

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

Future undesirable or unacceptable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous CAR T therapies and those under development have shown frequent rates of CRS, neurotoxicity, serious infections, prolonged cytopenia and hypogammaglobulinemia, hemophagocytic lymphohistiocytosis/macrophage activation syndrome (HLH/MAS) and adverse events have resulted in the death of patients. We expect similar adverse events for 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.

Our allogeneic CAR T cell product candidates may also cause unique adverse events related to the differences between the donor and patients, such as GvHD or infusion reactions. In addition, we utilize a lymphodepletion regimen, which generally includes fludarabine, cyclophosphamide and ALLO-647, that may cause serious adverse events. For instance, because the regimen will cause a transient and sometimes prolonged immune suppression, patients will have an increased risk of infection that may be unable to be cleared by the patient and ultimately lead to other serious adverse events or death. Our lymphodepletion regimen has caused and may also cause prolonged cytopenia and aplastic anemia. We are also exploring various dosing strategies for lymphodepletion in our clinical trials, such as higher and lower dosing of ALLO-647 in combination with fludarabine and/or cyclophosphamide and dosing with and without ALLO-647, which may increase the risk of serious adverse events.

In our and Servier's clinical trials of allogeneic CAR T product candidates, the most common severe or life-threatening adverse events resulted from cytokine release syndrome, 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. For instance, we observed a chromosomal abnormality that led to a previous clinical hold on our clinical trials. While our investigation concluded that the chromosomal abnormality had no clinical significance and was unrelated to our manufacturing process, our manufacturing 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.

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

***Phase 1 data from our clinical trials is limited and may change as more patient data become 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 become 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 ALPHA2 trial design is based on data from a limited number of patients treated with various doses of ALLO-501 or ALLO-501A manufactured using the Alloy process, and the larger Phase 2 ALPHA2 trial may not repeat the Phase 1 results. 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 to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.***

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

In addition, we submitted a standalone cross-reference IND for ALLO-647, which is being used as part of lymphodepletion in all our clinical trials. While our IND has been accepted, we have to update the IND for any new IND or IND amendment relating to our allogeneic CAR T cell product candidates. Any regulatory issues related to the review of our ALLO-647 IND updates or to the development of ALLO-647 could delay 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 suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required institutional review board (IRB) approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents uncertain or unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practice (GCP) requirements or applicable regulatory guidelines in other countries;
- delays or failures in the transfer of manufacturing processes to any contract manufacturing organization (CMO) 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
- 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, epidemic or future resurgences of COVID-19 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 CMO to our manufacturing facility, we will be required to meet certain regulatory conditions, such as establishing comparability with the product candidates manufactured at our CMO, 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.

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

For our clinical trials of our product candidates, we contract or will contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved, on a commercial basis could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. For example, as we progress the ALPHA2 and EXPAND 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. Additionally, it may be difficult to enroll the EXPAND trial as some clinical trial sites have declined to participate in the randomized design. 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. The COVID-19 pandemic, including the travel and business restrictions imposed by government authorities in response to the pandemic, resulted in, and a resurgence of COVID-19 or future epidemics or pandemics may result in, reduced enrollment and challenges to related clinical trial activities. The enrollment of patients may be more difficult, such as due to the perceptions of the safety of our clinical trials due to the previous clinical hold, and will depend on many factors, including:

- the patient eligibility criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to study sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- the competition from approved products in the same or other lines of therapy and and/or disease indication and from product candidates in other clinical trials; and

- the risk that patients enrolled in clinical trials will drop out of the trials before the infusion of our product candidates or trial completion.

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

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, 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. This 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 to the cutoff value. 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 about the expression of the molecule on tumor tissue. 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. 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 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 R/R 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 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 expect to initially seek approval of our product candidates in this setting. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment. 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 approved therapies. We are also targeting 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 in a position to receive second or later lines of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these 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. For instance, we expect ALLO-501A to initially target a small patient population that suffers from R/R NHL. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications.

***Our 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.***

We utilize an anti-CD52 monoclonal antibody as part of a lymphodepletion regimen to be infused prior to infusing our product candidates. While we believe an anti-CD52 antibody 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 such engineered allogeneic T cells can actively target and destroy cancer cells, the antibody may not have the benefits that we anticipate and could have adverse effects. For instance, our lymphodepletion regimen, including using an anti-CD52 antibody, will cause immune suppression that can be of unpredictable depth and duration and that may be associated with an increased risk of infection, such as to common viral or bacterial or opportunistic pathogens, that may be unable to be cleared and ultimately lead to other serious adverse events or death.

In the prior CALM and PALL trials, a commercially available monoclonal antibody, alemtuzumab, that binds CD52 was used. Alemtuzumab is known to have risk of causing certain adverse events. In 2020, the EMA completed a pharmacovigilance review of alemtuzumab in the context of the treatment of multiple sclerosis following reports of immune-mediated conditions and problems affecting the heart and blood vessels, including fatal cases. The EMA recommended that alemtuzumab should not be used in patients with certain heart, circulation or bleeding disorders or in patients who have autoimmune disorders other than multiple sclerosis. The EMA also recommended that alemtuzumab only be given in a hospital with ready access to intensive care facilities and specialists who can manage serious adverse reactions. Based on the recommendations, we have added relevant new safety information to certain of our clinical trial documentation, including informed consent forms. Our product candidates will also continue to be administered at specialized centers, which are experienced at managing patients with advanced malignancies as well as toxicities associated with immunomodulatory therapies. We will continue to monitor any new safety information that will be reported or added to the product labels of alemtuzumab. 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 higher and lower dosing of ALLO-647 in combination with fludarabine and cyclophosphamide, which may increase the risk of serious adverse events. Additionally, our experimental lymphodepletion regimens may show different safety profiles when paired with different allogeneic CAR T product candidates such that regimens deemed safe with one CAR T product candidate may be determined to be associated with unacceptable toxicity when combined with another CAR T candidate or with the same candidate in a different patient population. If observed, these differences may require additional clinical exploration and may cause delays in the execution or termination of development campaigns. See the section entitled "Business —Product Pipeline and Development Strategy" included in 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 product candidates would be significantly delayed.

***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 CMO, 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 CMO, including the inability to satisfy demands for any of our product candidates. While we believe the manufacturing and processing approaches are appropriate to support our clinical product development, 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 clinical trial and potential commercial production and worldwide distribution of allogeneic CAR T cell products for blood cancers and solid tumors. We decided to initiate the Phase 2 trial of ALLO-501A with material manufactured utilizing the Alloy process at our CMO, rather than material manufactured at our manufacturing facility that did not use the Alloy process. Introducing any product manufactured at our manufacturing facility into an ongoing clinical trial would be subject to FDA review, and may result in increased costs and delays in conducting such trial, submitting a biologics license application (BLA) and/or gaining FDA approval. Similar conditions may apply if we make process changes to our product candidates, as 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 CMO or at our own manufacturing facility could delay our clinical trials.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates, and the actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates. The commercial dose and treatment regimen may affect our ability to scale and will affect our cost per dose. For instance, because our anti-BCMA product candidates may require a higher dose than ALLO-501A, it is possible that it may be more difficult to scale production of our anti-BCMA product candidates to meet demand. As a result, we may never be able to develop a commercially viable product. Our manufacturing facility will also require FDA approval before it can be used for commercial production, which we may never obtain. Even if approved, we would be subject to ongoing periodic unannounced inspection by the FDA, EMA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP, and other government regulations.

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

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

We may also experience manufacturing difficulties due to resource constraints or as a result of labor disruptions, such as due to a future COVID-19 resurgence, 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. In addition, our enrollment timelines for ALLO-501A depend on initiating clinical trial sites outside of the United States. 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 and shipping the product candidate to the patient abroad;
- 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 resurgences of COVID-19 or 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 Therapeutics Inc. (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, and our Executive Vice President, Chief Technical Officer. Our General Counsel and Chief Financial Officer resigned effective March 31, 2023 and August 2, 2023, respectively, and we are currently recruiting for their replacements. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

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

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

***We have grown rapidly and 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. As our product candidates advance toward commercialization, we expect to hire employees in areas that include sales and marketing. Future growth imposes significant added responsibilities on members of management, including:

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

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

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

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

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

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

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

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

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, including our acquisition of CAR T cell assets from Pfizer, licenses with Collectis, Servier, Notch, Antion, 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;
- 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. may face difficulties manufacturing, 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.

***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 June 30, 2023, we had \$544.5 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. 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.

***If our security measures, or those of our CROs, CMOs, collaborators, contractors, consultants or other third parties upon whom we rely, are 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 may collect, process, receive, store, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively processing) proprietary, confidential and sensitive information, including personal data (including health information), intellectual property, trade secrets, and proprietary business information owned or controlled by ourselves or other parties. We may also share or receive sensitive information with our partners, CROs, CMOs, or other third parties. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may also experience adverse consequences.

Our internal computer systems and those of our CROs, CMOs, collaborators, contractors, consultants or other third parties are vulnerable to damage from computer viruses, unauthorized access, cybersecurity threats, and telecommunication and electrical failures. In addition, as many of our employees work from home at least part of the time and utilize network connections outside our premises, this poses increased risks to our information technology systems and data. Cyberattacks, malicious internet-based activity, and online and offline fraud are prevalent and are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. These threats come from a variety of sources, including traditional computer "hackers," "hacktivists," organized criminal threat actors, threat actors, personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce and distribute our product candidates. We and the third parties upon which we rely are subject to a variety of evolving threats, including social-engineering attacks (including through phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service (such as credential stuffing), credential harvesting, social engineering attacks (including through phishing attacks), viruses, ransomware, supply chain attacks, personnel misconduct or error and other similar threats. We may also be the subject of software bugs, server malfunction, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures or other similar issues. In particular, 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. Similarly, 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. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

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

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

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

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

We may be unable to detect 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. Despite our efforts to identify and remediate exploitable critical vulnerabilities, if any, in our information technology systems, our efforts may not be successful. 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.

Applicable data protection laws, privacy policies and data protection obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may also experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms.

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, 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.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions,

which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

In addition to the business disruptions caused by the COVID-19 pandemic or cybersecurity attacks described above, our operations, and those of our CMOs, CROs, clinical trial sites and other contractors and consultants, could be subject to other disruptions, including those caused by earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, tsunamis, typhoons, fires, extreme weather conditions, medical epidemics, future resurgences of COVID-19, wars and other geopolitical conflicts (such as Russia military action against Ukraine), bank failures, 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. While the U.S. Department of Treasury, FDIC and Federal Reserve Board have implemented a program to provide up to \$25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program, there is no guarantee that such programs will be sufficient. Additionally, 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. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co.

While we have not experienced any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations as a result of the matters relating to SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank, uncertainty remains over liquidity concerns in the broader financial services industry, and our business, our business partners or industry as a whole may be adversely impacted in ways that we cannot predict at this time.

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

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

above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

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

We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to fail, we could lose all or a portion of amounts held in excess of such insurance limitations. As noted above, the FDIC recently took control of SVB, Signature Bank, Silvergate Capital Corp and First Republic Bank. 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.

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

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

***We are subject to stringent and changing privacy laws, regulations and standards as well as policies, contracts and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to enforcement or litigation (that could result in 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 collect, receive, store, process, use, generate, transfer, disclose, make accessible, protect, secure, dispose of, transmit and share (collectively, processing) personal data and other sensitive information, including, but not limited to, proprietary and confidential business information, trade secrets, intellectual property, and information we collect about patients in connection with clinical trials. Accordingly, we are, or may become, subject to numerous federal, state, local and international 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 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 and other similar laws (e.g., wiretapping laws). For example, the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH), and their respective implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH, through its implementing regulations, makes certain of HIPAA's privacy and security standards directly applicable to business associates, defined as a person or organization, other than a member of a covered entity's workforce, that creates, receives, maintains or transmits protected health information for or on behalf of a covered entity for a function or activity regulated by HIPAA as well as their covered subcontractors.

In addition, the California Consumer Privacy Act (CCPA) applies to personal information of consumers, business representatives, and employees, and creates individual privacy rights and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide disclosures to California consumers, affords California residents certain rights related to their personal data, including the right to opt-out of certain sales of personal data, and allow for a new cause of action for certain data breaches. Although there are limited exemptions for clinical trial data under the CCPA, as our business progresses, the CCPA may become applicable and significantly impact our business activities and exemplifies the vulnerability of our business to evolving regulatory environment related to personal data and protected health information. Furthermore, the California Privacy Rights Act of 2020 (CPRA), effective January 1, 2023, expands the CCPA's requirements, including by applying to personal information of business representatives and employees and establishing a new regulatory agency to implement and enforce the law. In addition, other



states, such as Virginia and Colorado, have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. Additionally, several states and localities have enacted statutes banning or restricting the collection of biometric information. Moreover, data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the United States, there are an increasing number of laws, regulations and industry standards concerning 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), and China's Personal Information Protection Law (PIPL) impose strict requirements for processing personal data. Failure to comply with the requirements of the EU GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, other administrative penalties, and 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. If we cannot implement a valid compliance mechanism for cross-border data transfers, we may face increased exposure to regulatory actions, substantial fines, and injunctions against processing or transferring personal data from Europe or other foreign jurisdictions. The inability to import personal data to the United States could significantly and negatively impact our business operations, including by limiting our ability to conduct clinical trial activities in Europe and elsewhere; limiting our ability to collaborate with parties that are subject to such cross-border data transfer or localization laws; or requiring us to increase our personal data processing capabilities and infrastructure in foreign jurisdictions at significant expenses. European regulators have also ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply. We are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. If any of our privacy policies 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.

Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. 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 all applicable privacy and security obligations, we may at times fail to do so or may 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. For example, any failure by a third-party service provider to comply with applicable law, regulations, or contractual obligations could result in adverse effects, including inability to or interruption in our ability to operate our business and proceedings against us by governmental entities or others. If we 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. These consequences may include, but are not limited to, government enforcement actions (e.g., investigations, fines, penalties, audits and inspections, and similar); litigation (including class-related claims); additional reporting requirements and/or oversight; temporary or permanent bans on all or some processing of personal data; orders to destroy or not use personal data; and imprisonment of company officials. Any of these events could have a material adverse effect on our reputation, business, or financial condition.

***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.

***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 losses is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to federal tax laws. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. As a result of our IPO in October 2018 and private placements and other transactions that have occurred since our incorporation, we may have experienced an "ownership change". We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. We anticipate incurring significant additional net losses for the foreseeable future, and our ability to utilize net operating loss carryforwards associated with any such losses to offset future taxable income may be limited to the extent we incur future ownership changes. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could adversely affect our future cash flows.

**Risks Related to Our 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 good clinical practices (GCPs), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

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

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

Our product candidates are manufactured in the United States by our CMOs, and we manage all other aspects of the supply, including planning, CMO oversight, disposition and distribution logistics. For example, in the past, Servier was responsible for UCART19 manufacturing, and experienced UCART19 supply issues that limited its ability to recruit new patients. There can be no assurance that we will not experience supply or manufacturing issues in the future.

We do not have long-term agreements in place with CMOs for the manufacture of our cell therapies or of ALLO-647. If we are unable to contract with CMOs on acceptable terms or at all, our clinical development program would be delayed and our business would be significantly harmed.

While we have built our own manufacturing facility for cell therapies, the transition of manufacturing to our own facility will require significant investment and that we meet certain regulatory conditions, which may delay or extend our clinical trial timelines. We decided to initiate the Phase 2 trial of ALLO-501A with material manufactured utilizing the Alloy process at our CMO, rather than material manufactured at our manufacturing facility that did not use the Alloy process. Re-engaging our CMO to manufacture Alloy-based material is costly and the CMO may fail in manufacturing, such as due to the CMO having limited recent experience with manufacturing Alloy-based material.

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

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

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

Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Our current and potential future CMOs 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 CMOs have certain responsibilities for storage of raw materials and in the past have lost or failed to adequately store our raw materials. We also rely on third parties to store our released product candidates, and any failure to adequately store our product candidates could result in significant delay to our development timelines. Any additional or future damage or loss of raw materials or product candidates could materially impact our ability to manufacture and supply our product candidates. Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue.

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

***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 may be adversely impacted.\****

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

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

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

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

Our product candidates require many specialty raw materials, including viral vectors that deliver the CAR sequence and electroporation technology, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. We do not have contracts with many of the suppliers, and we may not be able to contract with them on acceptable terms, or at all. Many suppliers curtailed their operations during the COVID-19 pandemic, focused their operations on supporting COVID-19 therapies and vaccines, or have faced higher attrition, and our ability and the ability of our suppliers to source raw materials has been impacted. Accordingly, we may experience higher costs or delays in receiving, or fail to secure entirely, key raw materials to support clinical or commercial manufacturing. Certain raw materials also require third-party testing, and some of the testing service companies may not have capacity or be able to conduct the testing that we request.

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

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

Some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. For certain raw materials, we are in the process of qualifying a new supplier or a new manufacturing site from an existing supplier, which requires meeting regulatory requirements for such qualification, and 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. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. 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 commenced shipment of certain materials to our joint venture with Overland Pharmaceuticals (CY) Inc. in China and any violation by our joint venture in the use, manufacture, storage, handling and disposal under foreign law may subject us to additional liability.

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

## **Risks Related to Government Regulation**

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

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

CMC matters for the product, and any delay or failure in generating such data to meet the evolving CMC regulatory requirements would delay any BLA filing.

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

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

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent IRB;
- obtaining regulatory and other approvals to modify the conduct of a clinical trial;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial 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. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted or by the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions, lack of adequate funding to continue the clinical trial, or based on a recommendation by any Data Safety Monitoring Committee. The FDA's review of our data of our clinical trials may, depending on the data, also result in the delay, suspension or termination of one or more of our clinical trials, which would also delay or prevent the initiation of our other planned clinical trials. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

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

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

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

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

Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the EU a special committee called the Committee for Advanced Therapies (CAT) was established within the EMA in accordance with Regulation (EC) No 1394/2007 on advanced-therapy medicinal products (ATMPs) to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products. In this regard, on May 28, 2014, the EMA issued a recommendation that UCART19 be considered a gene therapy product under Regulation (EC) No 1394/2007 on ATMPs. We believe our other product candidates may 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 may disagree with our regulatory plan and we may fail to obtain regulatory approval of our CAR T cell product candidates.***

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

The FDA may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval 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. We believe

our accelerated approval strategy is warranted given the limited alternatives for patients with R/R cancers, but the FDA may ultimately require a Phase 3 clinical trial prior to approval, particularly since our product candidates represent a novel treatment. In addition, the standard of care may change with the approval of new products in the same indications that we are studying. This may result in the FDA or other regulatory agencies requesting additional studies to show that our product candidate is superior to the new products.

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

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

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

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

In addition, the FDA is requiring us to demonstrate the overall contribution of ALLO-647 to the benefit to risk ratio of the lymphodepletion regimen for ALLO-501A. We plan to assess ALLO-647 in a separate potentially registrational trial, the EXPAND trial, that we recently initiated. Some clinical trial sites have elected not to participate, and we cannot be certain when or whether we will be able to successfully enroll the EXPAND trial in a timely manner or that the outcome of this study will support FDA approval. For instance, enrolling two studies, ALPHA2 and EXPAND, that target the same indication may delay enrollment completion, and difference in data between the trials would introduce other regulatory review complications that would adversely impact both trials. Any delays to ALLO-647 approval could delay any approval or commercialization of our allogeneic CAR T cell product candidates.

***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 ALLO-501A and fast track designation (FTD) for ALLO-605 and ALLO-316. There is no assurance that we will be able to obtain RMAT



designation or FTD for any of our additional product candidates. RMAT designation and FTD 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 FTD 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 Biopharm (CY) Limited (Allogene Overland), a joint venture established by us and Overland Pharmaceuticals (CY) Inc. Increased negative public opinion or more restrictive government regulations either in the United States or internationally, would have a negative effect on our business or financial

condition and may delay or impair the development and commercialization of our product candidates or demand for such product candidates.

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

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

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

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

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

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- limitations or warnings contained in the labeling approved by the FDA;
- the timing of market introduction of our product candidates as well as competitive products;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- the willingness of patients to pay out-of-pocket in the absence of coverage and adequate reimbursement by third-party payors and government authorities;
- 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 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 ALLO-501A. 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 Collectis-Servier Agreement in ALL, and any failure by those parties to resolve such matters may have an adverse impact on us. In the future, we may also enter into additional license agreements that are material to the development of our product candidates.

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

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

If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product 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 ALLO-501A, and we hold the commercial rights to these product candidates in the United States. We also have an exclusive worldwide license from Collectis to its TALEN gene-editing technology for the development of allogeneic T cell product candidates directed against 15 different cancer antigens. The Servier Agreement gives us access to TALEN gene-editing technology for all product candidates under the agreement. Certain intellectual property which is covered by these agreements may have been developed with funding from the U.S. government. If so, our rights in this intellectual property may be subject to certain research and other rights of the government.

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

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

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

This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

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

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

***Confidentiality agreements with employees, Allogene Overland and third parties may not prevent unauthorized disclosure 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 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 plan 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 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;
- 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 controls over financial reporting are necessary for us to produce reliable financial statements. We are required, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, 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.

As a result of our public float on June 30, 2023, commencing on December 31, 2023 we will become a non-accelerated filer. 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 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. In response, 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, the conflict 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.**

*Appointment of Principal Financial Officer*

In connection with the previously announced resignation of Eric Schmidt, Ph.D., from his position as Chief Financial Officer, principal financial officer and principal accounting officer of the Company effective at the close of business August 2, 2023 (CFO Resignation), on August 1, 2023, our board of directors appointed David M. Chang, M.D., Ph.D, our current President and Chief Executive Officer and member of the board of directors, as principal financial officer of the Company, to be effective on August 3, 2023..

*Appointment of Principal Accounting Officer*

In connection with the CFO Resignation, on August 1, 2023, our board of directors appointed Jack Chen, our current Vice President and Controller, as principal accounting officer of the Company, to be effective on August 3, 2023.

Mr. Chen, 53, has served as our Vice President and Controller since July 2018. Prior to joining us, Mr. Chen served as Vice President of Finance, Corporate Controller at Tintri, Inc., a provider of storage systems and data management software, from February 2014 to June 2018. Previously, Mr. Chen served as Director of Finance and was responsible for the financial planning and analysis for Grass Valley, LLC from September 2013 to February 2014 and Host Analytics, Inc. from January 2011 to July 2013. Before that, Mr. Chen held various managerial roles in finance and accounting at Sonics, Inc., Micromuse Inc., CIPHERGEN Biosystems, Inc. and Tumbleweed Communications. Mr. Chen began his career at KPMG US LLP. He received a B.A. in Economics from the University of Chicago, and a Masters in Accountancy Science from the University of Illinois at Urbana Champaign, and is a former certified public accountant.

Mr. Chen will also enter into an indemnity agreement with the Company in the form previously filed with the SEC on October 2, 2018 as [Exhibit 10.1](#) to our Registration Statement on Form S-1, as amended.

There are no family relationships between Mr. Chen and any of our current or former directors or executive officers. Mr. Chen is not a party to any transaction that would require disclosure under Item 404(a) of Regulation S-K promulgated under the Securities Act of 1933, as amended.

**Item 6. Exhibits.**

<b>Exhibit number</b>	<b>Description of document</b>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
3.3	<a href="#">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).</a>
4.1	Reference is made to Exhibits <a href="#">3.1</a> , <a href="#">3.2</a> and <a href="#">3.3</a> .
4.2	<a href="#">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).</a>
4.3	<a href="#">Investors Rights Agreement, dated April 6, 2018, as amended September 5, 2018, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on September 14, 2018).</a>
31.1	<a href="#">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.</a>
31.2	<a href="#">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.</a>
32.1	<a href="#">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.</a>
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.

**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: August 2, 2023

By: /s/ David Chang  
David Chang, M.D., Ph.D.  
Chief Executive Officer  
(Principal Executive Officer)

Date: August 2, 2023

By: /s/ Eric Schmidt  
Eric Schmidt, Ph.D.  
Chief Financial Officer  
(Principal Financial and Accounting 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, 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 13(a)-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: August 2, 2023

*/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, Eric Schmidt, 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 13(a)-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: August 2, 2023

*/s/ Eric Schmidt*

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Eric Schmidt, Ph.D.  
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 June 30, 2023 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, Eric Schmidt, Ph.D., 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: August 2, 2023

*/s/ David Chang*

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

Date: August 2, 2023

*/s/ Eric Schmidt*

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Eric Schmidt, Ph.D.  
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.