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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38693

Allogene Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	ALLO	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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

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

As of May 3, 2021, the registrant had 141,538,421 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)

	March 31, 2021	December 31, 2020
Assets		(1)
Current assets:		
Cash and cash equivalents	$ 236,865	$ 183,351
Short-term investments	462,716	644,559
Prepaid expenses and other current assets	16,480	17,220
Total current assets	716,061	845,130
Long-term investments	264,573	204,208
Operating lease right-of-use asset	40,189	41,295
Property and equipment, net	123,146	118,840
Restricted cash	9,449	9,449
Other long-term assets	6,275	5,169
Equity method investment	19,351	3,738
Total assets	$ 1,179,044	$ 1,227,829
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 14,875	$ 10,390
Accrued and other current liabilities	39,735	44,938
Deferred revenue	239	38,992
Total current liabilities	54,849	94,320
Lease liability, non-current	51,625	50,809
Other long-term liabilities	2,791	3,083
Total liabilities	109,265	148,212
Commitments and Contingencies (Notes 6 and 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value: 10,000,000 shares authorized as of March 31, 2021 and December 31, 2020; no shares were issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value: 200,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 141,470,075 and 140,474,305 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	141	140
Additional paid-in capital	1,749,097	1,725,552
Accumulated deficit	(679,358)	(646,343)
Accumulated other comprehensive (loss) income	(101)	268
Total stockholders' equity	1,069,779	1,079,617
Total liabilities and stockholders' equity	$ 1,179,044	$ 1,227,829

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

(1) The balance sheet as of December 31, 2020 is derived from the audited financial statements as of that date.

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

	Three Months Ended March 31,	
	2021	2020
Collaboration revenue - related party	$ 38,345	$ —
Operating expenses:		
Research and development	55,183	42,042
General and administrative	16,363	15,641
Total operating expenses	71,546	57,683
Loss from operations	(33,201)	(57,683)
Other income (expense), net:		
Interest and other income, net	511	3,261
Other expenses	(325)	(58)
Total other income (expense), net	186	3,203
Net loss	(33,015)	(54,480)
Other comprehensive income:		
Net unrealized gain (loss) on available-for-sale investments	(369)	465
Net comprehensive loss	$ (33,384)	$ (54,015)
Net loss per share, basic and diluted	$ (0.25)	$ (0.50)
Weighted-average number of shares used in computing net loss per share, basic and diluted	132,165,014	108,963,522

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (loss)	Total Stockholders' Equity
	Shares	Amount				
Balance - December 31, 2020	140,474,305	$ 140	$ 1,725,552	$ (646,343)	$ 268	$ 1,079,617
Issuance of common stock upon exercise of stock options and vesting of RSUs	897,744	1	4,059	—	—	4,060
Vesting of early exercised common stock	—	—	710	—	—	710
Stock-based compensation	—	—	16,792	—	—	16,792
Employee stock purchase plan	98,026	—	1,984	—	—	1,984
Net loss	—	—	—	(33,015)	—	(33,015)
Net unrealized loss on available-for-sale investments	—	—	—	—	(369)	(369)
Balance - March 31, 2021	141,470,075	$ 141	$ 1,749,097	$ (679,358)	$ (101)	$ 1,069,779

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount				
Balance - December 30, 2019	124,267,358	$ 124	$ 1,023,876	$ (396,122)	$ 1,145	$ 629,023
Issuance of common stock upon exercise of stock options and vesting of RSUs	339,775	—	303	—	—	303
Vesting of early exercised common stock	—	—	710	—	—	710
Stock-based compensation	—	—	14,215	—	—	14,215
Employee stock purchase plan	84,565	—	1,438	—	—	1,438
Issuance of common stock from public offering, net of commissions and offering costs of $0.3 million	570,839	1	14,844	—	—	14,845
Net loss	—	—	—	(54,480)	—	(54,480)
Net unrealized gain on available-for-sale investments	—	—	—	—	465	465
Balance - March 31, 2020	125,262,537	$ 125	$ 1,055,386	$ (450,602)	$ 1,610	$ 606,519

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

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

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (33,015)	$ (54,480)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	16,792	14,215
Amortization of other intangible assets acquired	—	151
Depreciation and amortization	1,918	1,893
Net amortization/accretion on investment securities	1,911	(207)
Non-cash rent expense	2,007	718
Share of losses from equity method investments	325	64
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	740	2,552
Other long-term assets	(799)	(57)
Accounts payable	4,152	(1,044)
Accrued and other current liabilities	(4,314)	(3,913)
Deferred revenue	(38,753)	—
Other long-term liabilities	(292)	(701)
Net cash used in operating activities	(49,328)	(40,809)
Cash flows from investing activities:		
Purchases of property and equipment	(6,461)	(12,253)
Purchase of stock in equity method investment	(15,938)	—
Proceeds from maturities of investments	268,249	120,261
Purchase of investments	(149,052)	(123,015)
Net cash (used in) provided by investing activities	96,798	(15,007)
Cash flows from financing activities:		
Proceeds from issuance of common stock from ATM offering, net of commissions and issuance costs	—	14,845
Proceeds from issuance of common stock upon exercise of stock options	4,060	303
Proceeds from issuance of common stock under the employee stock purchase plan	1,984	1,438
Net cash provided by financing activities	6,044	16,586
Net change in cash, cash equivalents and restricted cash	53,514	(39,230)
Cash, cash equivalents and restricted cash — beginning of period	192,800	179,425
Cash, cash equivalents and restricted cash — end of period	$ 246,314	$ 140,195
Non-cash investing activities:		
Property and equipment purchases in accounts payable and accrued and other current liabilities	$ 8,299	$ 4,208
Capitalized cloud computing costs included in accounts payable and accrued and other current liabilities	$ 277	$ —
Supplemental disclosure:		
Cash paid for amounts included in the measurement of lease liabilities	$ (966)	$ (1,396)
Cash received for amounts related to tenant improvement allowances	$ 1,111	$ 532

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 and commercialization of genetically engineered allogeneic T cell therapies 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.

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 $964.2 million as of March 31, 2021. Since inception through March 31, 2021, the Company has incurred cumulative net losses of $679.4 million. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available when needed and 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 a period of at least one year from the date the accompanying unaudited condensed consolidated financial statements are filed with the Securities and Exchange Commission (SEC).

The Company cannot at this time predict the specific extent, duration, or full impact that the ongoing COVID-19 pandemic will have on its financial condition and operations, including ongoing and planned clinical trials. The impact of the COVID-19 pandemic on the financial performance of the Company will depend on future developments, including the duration and spread of the pandemic and related governmental advisories and restrictions. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain. If business conditions, financial markets and/or the overall economy are impacted for an extended period, the Company's results may be adversely affected.

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 March 31, 2021, the condensed consolidated statements of operations and comprehensive loss for the three months ended March 31, 2021 and 2020, the condensed consolidated statements of stockholders' equity as of March 31, 2021 and 2020, the condensed consolidated statements of cash flows for the three months ended March 31, 2021 and 2020, and the financial data and other financial information disclosed in the notes to the condensed consolidated financial statements are unaudited. The results of operations for the three months ended March 31, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021, 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, 2020, included in the Company's Annual Report on Form 10-K filed with the SEC on February 25, 2021.

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 stock options, 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 dictate. Actual results could differ from those estimates.

Significant Accounting Policies

There have been no significant changes to the accounting policies during the three months ended March 31, 2021, 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, with the exception of revenue recognition related to the collaboration revenue recognized in the three months ended March 31, 2021 and the recently adopted accounting pronouncements in the section below.

Revenue Recognition

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

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements (ASC 808) to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and, therefore, within the scope of Topic 606, Revenue from Contracts with Customers (ASC 606). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to Topic 606.

For elements of those arrangements that the Company determines should be accounted for under ASC 606, the Company assesses which activities in the collaboration agreements are performance obligations that should be accounted for separately and determine the transaction price of the arrangement, which includes the assessment of the probability of achievement of future milestones and other potential consideration. A performance obligation represents a promise in a contract to transfer a distinct good or service to a customer, which represents a unit of accounting in accordance with ASC 606. A performance obligation is considered distinct from other obligations in a contract when it provides a benefit to the customer either on its own or together with other resources that are readily available to the customer and is separately identified in the contract. The Company considers a performance obligation satisfied once the Company has transferred control of a good or service to the customer, meaning the customer has the ability to use and obtain the benefit of the good or service. A portion of the consideration should be allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. The total consideration which the Company expects to collect in exchange for the Company's products is an estimate and may be fixed or variable. The Company constrains the estimated variable consideration when it assesses it is probable that a significant reversal in the amount of cumulative revenue recognized may occur in future periods. The transaction price is re-evaluated, including the estimated variable consideration included in the transaction price and all constrained amounts, in each reporting period and as uncertain events are resolved or other changes in circumstances occur. The allocation of the transaction price is performed based on standalone selling prices, which are based on estimated amounts that the Company would charge for a performance obligation if it were sold separately. Revenue is recognized when, or as, performance obligations in the contracts are satisfied, in the amount reflecting the expected consideration to be received from the goods or services transferred to the customers. Funds received in advance are recorded as deferred revenue and are recognized as the related performance obligation is satisfied.

Recently Adopted Accounting Pronouncements

In January 2020, the FASB issued Accounting Standard Update No. 2020-01, *Investments – Equity Securities (Topic 321), Investments – Equity Method and Joint Ventures (Topic 323)*, which clarifies the interactions between Topics 321 and 323 in applying or discontinuing the equity method of accounting for investments. This guidance is effective for fiscal years beginning after December 15, 2020, with early adoption permitted. The Company adopted this standard on January 1, 2021 on a prospective basis. Adoption of the new guidance had no significant impact on the Company's condensed consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

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

3. Fair Value Measurements

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

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

There were no Level 3 assets or liabilities as of March 31, 2021 and as of December 31, 2020.

Financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of March 31, 2021 and as of December 31, 2020 are presented in the following tables:

	March 31, 2021			
	Level 1	Level 2	Level 3	Fair Value
	(in thousands)			
Financial Assets:				
Money market funds (1)	$ 176,627	$ —	$ —	$ 176,627
Commercial paper	—	39,993	—	39,993
Corporate bonds	—	221,891	—	221,891
U.S. treasury securities	390,318	—	—	390,318
U.S. agency securities	—	75,087	—	75,087
Total financial assets	$ 566,945	$ 336,971	$ —	$ 903,916

	December 31, 2020			
	Level 1	Level 2	Level 3	Fair Value
	(in thousands)			
Financial Assets:				
Money market funds (1)	$ 102,039	$ —	$ —	$ 102,039
Commercial paper	—	58,975	—	58,975
Corporate bonds	—	262,757	—	262,757
U.S. treasury securities	446,996	—	—	446,996
U.S. agency securities	—	80,039	—	80,039
Total financial assets	$ 549,035	$ 401,771	$ —	$ 950,806

(1) Included within cash and cash equivalents on the Company’s condensed consolidated balance sheets

4. Financial Instruments

The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of March 31, 2021 and as of December 31, 2020 are presented in the following tables:

	March 31, 2021			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 176,627	$ —	$ —	$ 176,627
Commercial paper	39,986	7	—	39,993
Corporate bonds	221,738	184	(31)	221,891
U.S. treasury securities	390,132	194	(8)	390,318
U.S. agency securities	75,092	15	(20)	75,087
Total cash equivalents and investments	$ 903,575	$ 400	$ (59)	$ 903,916
Classified as:				
Cash equivalents				$ 176,627
Short-term investments				462,716
Long-term investments				264,573
Total cash equivalents and investments				$ 903,916

	December 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 102,039	$ —	$ —	$ 102,039
Commercial paper	58,969	8	(2)	58,975
Corporate bonds	262,349	444	(36)	262,757
U.S. treasury securities	446,726	282	(12)	446,996
U.S. agency securities	80,012	30	(3)	80,039
Total cash equivalents and investments	$ 950,095	$ 764	$ (53)	$ 950,806
Classified as:				
Cash equivalents				$ 102,039
Short-term investments				644,559
Long-term investments				204,208
Total cash equivalents and investments				$ 950,806

As of March 31, 2021, the remaining contractual maturities of available-for-sale securities were less than 3 years. There have been no significant realized losses on available-for-sale securities for the periods presented. As of March 31, 2021, unrealized losses on available-for-sale investments 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 marketable securities are due to market factors. As of March 31, 2021 and December 31, 2020, securities with a fair value of zero and $5.0 million respectively, were in a net unrealized loss position for more than 12 months. To date, the Company has not recorded any impairment charges on marketable securities.

5. Balance Sheet Components

Property and Equipment, Net

Property and Equipment consist of the following:

	March 31, 2021	December 31, 2020
	(In thousands)	
Construction in progress	$ 73,339	$ 68,944
Leasehold improvements	31,518	31,518
Laboratory equipment	25,112	23,810
Computers equipment and purchased software	4,271	4,088
Furniture and fixtures	3,731	3,388
Total	137,971	131,748
Less: accumulated depreciation	(14,825)	(12,908)
Total property and equipment, net	$ 123,146	$ 118,840

6. License Agreements

Asset Contribution Agreement with Pfizer

In April 2018, the Company entered into an Asset Contribution Agreement (the Pfizer Agreement) with Pfizer pursuant to which the Company acquired certain assets, including certain contracts and intellectual property for the development and administration of chimeric antigen receptor (CAR) T cells for the treatment of cancer. The Company is required to make milestone payments upon successful completion of regulatory and sales milestones on a target-by-target basis for the targets including CD19 and B-cell maturation antigen (BCMA), covered by the Pfizer Agreement. The aggregate potential milestone payments upon successful completion of various regulatory milestones in the United States and the European Union are $30.0 million or $60.0 million, depending on the target, with aggregate potential regulatory and development milestones of up to $840.0 million, provided that the Company is not obligated to pay a milestone for regulatory approval in the European Union for an anti-CD19 allogeneic CAR T cell product, to the extent Servier has commercial rights to such territory. The aggregate potential milestone payments upon reaching certain annual net sales thresholds in North America, Europe, Asia, Australia and Oceania (the Territory) for a certain number of targets covered by the Pfizer Agreement are $325.0 million per target. The sales milestones in the foregoing sentence are payable on a country-by-country basis until the last to expire of any Pfizer Royalty Term, as described below, for any product in such country in the Territory. In October 2019, the Territory was expanded to all countries in the world. No milestone or royalty payments were made in the three months ended March 31, 2021 and 2020 respectively.

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 or that use certain Pfizer intellectual property and for which an investigational new drug application (IND) is first filed on or before April 6, 2023. The Company's royalty obligation with respect to a given product in a given country begins upon the first sale of such product in such country and ends on the later of (i) expiration of the last claim of any applicable patent or (ii) 12 years from the first sale of such product in such country.

Research Collaboration and License Agreement with Cellectis

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

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

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

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

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

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

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

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

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

All costs the Company incurred in connection with this agreement were recognized as research and development expenses. For the three months ended March 31, 2021 and March 31, 2020, $5.0 million and 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 ($82.7 million), respectively. The foregoing milestones are subject to certain adjustments if the Company obtains rights for certain products outside of the United States upon Servier's election not to pursue such rights.

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

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

For the three months ended March 31, 2021 and 2020, the Company recorded $3.9 million and $1.0 million, respectively, of net cost recoveries under the cost-sharing terms of the Servier Agreement as a reduction to research and development expenses. As of March 31, 2021 and December 31, 2020, amounts due from Servier of $4.5 million and $3.8 million, respectively, were recorded in other current assets in the accompanying condensed consolidated balance sheets.

Research Collaboration and License Agreement with Notch

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

The Notch Agreement includes a research collaboration to conduct research and pre-clinical development activities to generate engineered cells directed to Allogene's exclusive targets, which will be conducted in accordance with an agreed research plan and budget under the oversight of a joint development committee. Allogene will reimburse Notch's costs incurred in accordance with such plan and budget. The term of the research collaboration will expire upon the earlier of (i) the fifth anniversary of the date of the Notch Agreement, (ii) at Allogene's election, following the joint development committee's determination that for each exclusive target, Notch has met certain success criteria, or (iii) the joint development committee's determination that the research collaboration cannot be reasonably pursued against any exclusive target due to technical infeasibility or safety issues.

In connection with the execution of the Notch Agreement, Allogene made an upfront payment to Notch of $10.0 million in return for a license to access Notch's technology in order to conduct research pursuant to the Notch Agreement. The Company recognized a research and development expense of $10 million during the year ended December 31, 2019 as the license had no foreseeable alternative future use. In addition, Allogene made a $5.0 million investment in Notch's series seed convertible preferred stock, resulting in Allogene having a 25% ownership interest in Notch's outstanding capital stock on a fully diluted basis immediately following the investment. In connection with this investment, David Chang, M.D., Ph.D., the Company's President, Chief Executive Officer and Board member, was appointed to Notch's Board of Directors. In February 2021, the Company made an additional $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. The Company did not have a controlling interest in Notch as of March 31, 2021, 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 months ended March 31, 2021 and 2020, the Company recorded $1.2 million and $0.3 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.

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 December 31, 2020, 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.

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 March 31, 2021 and December 31, 2020, 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 months ended March 31, 2021 the Company recognized $38.3 million of collaboration revenue, primarily related to the license of intellectual property and delivery of the know-how performance obligation which was delivered in the first quarter of 2021.

7. Commitments and Contingencies

Leases

In August 2018, the Company entered into an operating lease agreement for new office and laboratory space which consists of approximately 68,000 square feet located in South San Francisco, California. The lease term is 127 months beginning August 2018 through February 2029 with an option to extend the term for another seven years which is 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. The rent payments began on March 1, 2019 after an abatement period.

In October 2018, the Company entered into an operating lease agreement for new office and laboratory space which consists of 14,943 square feet located in South San Francisco, California. The lease term is 124 months beginning November 2018 through February 2029, with an option to extend the term for another seven years which is 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 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 has a term of 188 months and commenced 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 is entitled to a tenant improvement allowance of $2.9 million for costs related to the design and construction of certain Company improvements and has received $2.7 million of tenant improvement allowances up to March 31, 2021.

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 $5.2 million and $4.3 million as of March 31, 2021 and December 31, 2020, respectively.

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

	March 31, 2021	December 31, 2020
Operating lease liabilities		
Current portion included in accrued and other current liabilities	$ 3,061	$ 2,974
Long-term portion of lease liabilities	51,625	50,809
Total operating lease liabilities	$ 54,686	$ 53,783

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

	Three Months Ended March 31,	
	2021	2020
Operating lease cost	$ 1,862	$ 1,868
Variable lease cost	327	210
Total lease costs	$ 2,189	$ 2,078

Cash paid for amounts included in the measurement of lease liabilities for the three months ended March 31, 2021 was $1.0 million and was included in net cash used in operating activities in our condensed consolidated statements of cash flows.

The undiscounted future lease payments under the lease agreements as of March 31, 2021 were as follows:

Year ending December 31:	(in thousands)
2021 (remaining 9 months)	$ 5,044
2022	7,917
2023	8,168
2024	8,430
2025	8,509
2026 and thereafter	48,143
Total undiscounted lease payments	86,211
Less: Present value adjustment	(31,200)
Less: Tenant improvement allowance	(325)
Total	$ 54,686

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, we use our estimated incremental borrowing rate. The weighted average

discount rate used to determine the operating lease liability was 8.40%. As of March 31, 2021, the weighted average remaining lease term for our operating leases is 10.22 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 is expected to commence in the second quarter of 2021. 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 disclosed as restricted cash in the condensed consolidated balance sheet as of March 31, 2021.

The Company has entered into certain license agreements for intellectual property which is used as part of our development and manufacturing processes. Each of these respective agreements are generally cancellable by the Company. These agreements require payment of annual license fees and may include conditional milestone payments for achievement of specific research, clinical and commercial events, and royalty payments. The timing and likelihood of any significant conditional milestone payments or royalty payments becoming due was not probable as of March 31, 2021.

The Company enters into contracts in the normal course of business that includes arrangements with clinical research organizations, vendors for preclinical research and vendors for manufacturing. These agreements generally allow for cancellation with notice. As of March 31, 2021, the Company had non-cancellable purchase commitments of $4.1 million.

8. Equity Method Investment

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.

The Company’s total equity investment in Notch as of March 31, 2021 and December 31, 2020 was $19.4 million and $3.7 million, respectively, and the Company accounted for the investment using the equity method of accounting.

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 under which it acquired shares of Allogene Overland’s Seed Preferred Shares representing a 49% ownership interest as partial consideration 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 March 31, 2021 and December 31, 2020, respectively.

The Company’s equity investment in Allogene Overland as of March 31, 2021 and December 31, 2020 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 31 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 shall not have an exercise price less than 100% of the fair market value of the Company's common stock on the grant date. 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.

As of March 31, 2021, there were 17,212,410 shares reserved by the Company under the 2018 Plan for the future issuance of equity awards.

Stock Option Activity

The following summarizes option activity under the 2018 Plan:

	Outstanding Options			
	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term	Aggregate intrinsic value
			(in years)	(in thousands)
Balance, December 31, 2020	10,434,034	$ 17.73	8.29	$ 93,149
Granted	1,617,078	34.04		
Exercised	(447,880)	8.95		
Forfeited	(496,070)	15.36		
Balance, March 31, 2021	11,107,162	$ 20.57	8.23	$ 166,162
Exercisable, March 31, 2021	7,423,034	$ 19.15	8.19	$ 120,201
Vested and expected to vest, March 31, 2021	11,107,162	$ 20.57	8.23	$ 166,162

The aggregate intrinsic values of options outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the closing price of the Company's common stock on the Nasdaq Global Select Market on March 31, 2021. For the three months ended March 31, 2021, the estimated weighted-average grant-date fair value of employee options granted was $21.41 per share. As of March 31, 2021, there was $102.9 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, 332 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:

	Three Months Ended March 31,	
	2021	2020
Expected term in years	6.06 - 6.08	6.07 - 6.09
Expected volatility	70.80%	71.42%
Expected risk-free interest rate	0.60% - 1.16%	0.80% - 1.65%
Expected dividend	0%	0%

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

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

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

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

Restricted Stock Unit Activity

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

	Outstanding Restricted Stock Units			
	Restricted Stock Units	Weighted-Average Fair Value at Date of Grant per Share	Weighted Average Remaining Vesting Life	Aggregate Intrinsic Value
			(in years)	(in thousands)
Unvested December 31, 2020	2,493,920	$ 26.14	1.66	$ 62,947
Granted	1,139,363	33.94	2.45	
Vested	(439,652)	23.44		
Forfeited	(140,218)	25.53		
Unvested March 31, 2021	3,053,413	$ 29.47	2.01	$107,785
Vested and expected to vest, March 31, 2021	3,053,413	$ 29.47	2.01	$107,785

As of March 31, 2021, there was $82.0 million of unrecognized stock-based compensation related to unvested restricted stock units, which is expected to be recognized over a weighted-average period of 3 years, 88 days.

Total stock-based compensation 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 March 31,	
	2021	2020
Research and development	$ 7,920	$ 6,657
General and administrative	8,872	7,558
Total stock-based compensation	$ 16,792	$ 14,215

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. As of March 31, 2021 and December 31, 2020 there was $2.8 million and $2.8 million recorded in accrued and other liabilities and $0.4 million and $1.1 million 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 since the exercise date 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). During the three months ending March 31, 2021, the Company recognized $38.3 million of collaboration revenue from Allogene Overland under this arrangement.

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. The Company's executive chairman, Arie Belldegrun, M.D., FACS, is a trustee of the Belldegrun Family Trust, which controls Bellco Capital Advisors Inc. The total right of use asset and associated liability recorded related to this related party lease was $0.1 million and $0.1 million for the three months ended March 31, 2021 and 2020, respectively.

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 Chairman of the board of directors, and a director of the Company to provide various managerial, administrative, accounting and financial services to the Company. The costs incurred for services provided under this agreement were $0.1 million and $0.1 million for the three months ended March 31, 2021 and 2020, 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. Belldegrun 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 $37,500 per month in arrears commencing January 2020 and $38,583 per month in arrears commencing January 2021. 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 cost incurred for services provided and out-of-pocket expenses incurred under this consulting agreement were $0.2 million and $0.2 million for the three months ended March 31, 2021 and 2020, respectively.

11. Income Taxes

The Company has a history of losses, and expects to record a loss in 2021. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

12. Net Loss Per Share

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

	March 31,	
	2021	2020
Stock options to purchase common stock	11,107,162	11,627,389
Restricted stock units subject to vesting	3,053,413	2,534,671
Expected shares to be purchased under Employee Stock Purchase Plan	258,986	226,459
Founder's shares of common stock subject to future vesting	6,057,696	12,115,382
Early exercised stock options subject to future vesting	1,423,350	2,678,501
Total	21,900,607	29,182,402

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, 2020 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, 2020 (Annual Report), which was filed with the Securities and Exchange Commission (SEC) on February 25, 2021. 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 and commercialization of genetically engineered allogeneic T cell therapies 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 the 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, while Servier retains exclusive rights for these product candidates for all other countries. ALLO-501 and ALLO-501A use Cellectis S.A. (Cellectis) technologies under which Servier holds an exclusive worldwide license from Cellectis.

We are sponsoring a Phase 1 clinical trial (the ALPHA trial) of ALLO-501 in patients with 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. We initiated a Phase 1/2 clinical trial for ALLO-501A (the ALPHA2 trial) in the second quarter of 2020. We plan to report updated data from the ALPHA trial and initial data from the ALPHA2 trial on May 19, 2021. We also plan to continue to progress the ALPHA and ALPHA2 trials and, subject to data, we plan to progress to the Phase 2 portion of the ALPHA2 trial by the end of 2021.

We are progressing three programs targeting B-cell maturation antigen (BCMA) for the treatment of multiple myeloma. We initiated a Phase 1 clinical trial (the UNIVERSAL trial) of ALLO-715 in adult patients with R/R multiple myeloma in the third quarter of 2019 and presented initial clinical data at the American Society of Hematology annual meeting in December 2020. Based on preliminary clinical data, the U.S. Food and Drug Administration (FDA) granted Regenerative Medicine Advanced Therapy (RMAT) designation for ALLO-715 for the treatment of adult patients with R/R multiple myeloma after three or more prior lines of therapies. RMAT does not change the standards for approval but may expedite the development or approval process. In January 2020, we entered into a clinical trial collaboration agreement with SpringWorks

Therapeutics, Inc. (SpringWorks) to evaluate ALLO-715 in combination with SpringWorks' investigational gamma secretase inhibitor, nirogacestat, in patients with R/R multiple myeloma. In the first quarter of 2021, we initiated this combination trial as part of the UNIVERSAL trial. Finally, we are advancing ALLO-605, an allogeneic CAR T cell product candidate targeting BCMA and our first product candidate to incorporate our TurboCAR technology. The FDA recently cleared our investigational new drug application (IND) to initiate a Phase 1 clinical trial (the IGNITE trial) of ALLO-605. We expect to initiate the IGNITE trial in mid-2021.

We recently initiated a 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).

We are continuing to enroll patients in the ALPHA trial, ALPHA2 trial, UNIVERSAL trial and TRAVERSE trial, however, enrollment of new patients in our trials and the ability to conduct patient follow-up is being adversely impacted by the COVID-19 pandemic. We have also limited the number of staff working at our facilities. The exact timing of delays and overall impact of the COVID-19 pandemic to our business, preclinical studies and clinical trials is currently unknown, and we are monitoring the pandemic as it continues to rapidly evolve.

Since inception, we have had significant operating losses. Our net losses were $33.0 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of $679.4 million. As of March 31, 2021, we had $964.2 million in cash and cash equivalents and investments. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses and general and administrative expenses will continue to increase.

Our Research and Development and License Agreements

Asset Contribution Agreement with Pfizer

In April 2018, we entered into an Asset Contribution Agreement (Pfizer Agreement) with Pfizer pursuant to which we acquired certain assets and assumed certain liabilities from Pfizer, including agreements with 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 the Servier Agreement to develop, manufacture and commercialize certain allogeneic anti-CD19 CAR products, including UCART19, in the United States with the option to obtain the rights over certain additional allogeneic anti-CD19 CAR product candidates and for allogeneic CAR T cell product candidates directed against one additional target. In April 2018, Pfizer assigned the agreement to us pursuant to the Pfizer Agreement. In October 2019, we agreed to waive our rights to the one additional target. 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, 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. Immediately following this transaction, our share in Notch was 20.7% 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).

Pursuant to the Share Purchase Agreement, we acquired Seed Preferred Shares in Allogene Overland representing 49% of Allogene Overland's outstanding stock as partial consideration for the License Agreement, and Overland acquired Seed Preferred Shares representing 51% of Allogene Overland's outstanding stock for $117.0 million in upfront and certain quarterly cash payments, to support operations of Allogene Overland. As of March 31, 2021, Allogene 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, we 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, we 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.

Promises that we 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, we 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. We constrain the estimated variable consideration when we assess 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. We re-evaluate 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 our joint venture and equity method accounting upon formation of the joint venture, and as such, were excluded from the transaction price. We 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 we 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. We recognized $38.3 million of the upfront payment of $40.0 million as collaboration revenue for the quarter ending on March 31, 2021. 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.

Components of Results of Operations

Revenues

As of March 31, 2021, our revenue has been exclusively generated from our collaboration and license agreement with Allogene Overland Biopharm (CY) limited (Allogene Overland). See Notes 2 and 6 to our financial statements appearing elsewhere in this Quarterly Report for more information related to our recognition of revenue and the Allogene Overland agreement.

In the future, we may generate revenue from a combination of product sales, 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, milestone 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 and preclinical and clinical development, and manufacturing of our product candidates. Research and development expenses for the three months ended March 31, 2021 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 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 are required to reimburse Servier for 60% of the costs associated with the prior development of UCART19, including for the CALM and PALL clinical trials of UCART19. We accrue for costs incurred by monitoring the status of the CALM and PALL clinical trials and the invoices received from Servier. We adjust our accrual as actual costs become known. Servier is required to reimburse us for 40% of the costs associated with the development of ALLO-501 and ALLO-501A. Collaboration expenses and cost reimbursement are recorded on a net basis as a research and development expense in our condensed consolidated statements of operations and comprehensive loss.

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;
- 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, 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 the increased costs of operating as a public company, including additional compliance-related expenses as a result of no longer being an emerging growth 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 increased costs associated with being a public company such as expenses related to services associated with maintaining compliance with Nasdaq listing rules and SEC requirements, insurance and investor relations costs.

Interest and Other Income, Net

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

Other Expense

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

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

The following sets forth our results of operations for the three months ended March 31, 2021 and 2020 (dollars in thousands):

	Three Months Ended March 31,		Change	
	2021	2020	$	%
Collaboration revenue - related party	$ 38,345	$ —	$ 38,345	—
Operating expenses:				
Research and development	55,183	42,042	13,141	31 %
General and administrative	16,363	15,641	722	5 %
Total operating expenses	71,546	57,683	13,863	24 %
Loss from operations	(33,201)	(57,683)	24,482	(42)%
Other income (expense), net:				
Interest and other income, net	511	3,261	(2,750)	(84)%
Other expenses	(325)	(58)	(267)	460 %
Total other income (expense), net	186	3,203	(3,017)	(94)%
Loss before income taxes	(33,015)	(54,480)	21,465	(39)%
Income tax expense	—	—	—	—
Net Loss	$ (33,015)	$ (54,480)	$ 21,465	(39)%

Collaboration revenue - related party

Collaboration revenue was $38.3 million and zero for the three months ended March 31, 2021 and 2020, respectively. The increase of $38.3 million was due to collaboration revenue recognized pursuant to the license agreement with Allogene Overland.

Research and Development Expenses

Research and development expenses were $55.2 million and $42.0 million for the three months ended March 31, 2021 and 2020, respectively. The increase of $13.1 million was driven primarily by an increase in personnel related costs of $6.6 million, of which $1.3 million was increased stock-based compensation expense, an increase in external costs relating to the advancement of our product candidates of $5.1 million, and an increase in building rent and facilities costs of $1.7 million, offset by a decrease in travel related costs of $0.1 million due to the impact of the COVID-19 pandemic.

General and Administrative Expenses

General and administrative expenses were $16.4 million and $15.6 million for the three months ended March 31, 2021 and 2020, respectively. The net increase of $0.7 million was primarily due to an increase in personnel related costs of $1.8 million, of which $1.3 million was increased stock-based compensation expense, offset by a decrease in business expenses and professional service fees of $0.7 million and a decrease in building rent and facilities costs of $0.3 million.

Interest and Other Income, Net

Interest and other income, net was $0.5 million and $3.3 million for the three months ended March 31, 2021 and 2020, respectively. The decrease of $2.8 million was due to lower interest earned on our cash, cash equivalents and investments.

Liquidity, Capital Resources and Plan of Operations

To date, we have incurred significant net losses and negative cash flows from operations. As of March 31, 2021, we had $964.2 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 enable us to maintain our operations for a period of at least one year 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, and our June 2020 underwritten public offering. 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) 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, 2020, we sold an aggregate of 848,663 shares of common stock in ATM offerings resulting in net proceeds of $26.2 million. As of March 31, 2021, $167.3 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.

Our primary use of cash is to fund construction projects for our manufacturing facility and 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.

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 arrangements. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders’ rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise capital when needed, we will need to delay, reduce or terminate planned activities to reduce costs. Doing so will likely harm our ability to execute our business plans.

Cash Flows

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

	Three Months Ended March 31,	
	2021	2020
	(In thousands)	
Net cash (used in) provided by:		
Operating activities	$ (49,328)	$ (40,809)
Investing activities	96,798	(15,007)
Financing activities	6,044	16,586
Net increase in cash, cash equivalents and restricted cash	$ 53,514	$ (39,230)

Operating Activities

During the three months ended March 31, 2021, cash used in operating activities of $49.3 million was attributable to a net loss of $33.0 million, partially offset by non-cash charges of $23.0 million and an increase of $39.3 million in our net operating assets and liabilities. The non-cash charges consisted primarily of stock compensation expense of $16.8 million, non-cash rent expense of $2.0 million, depreciation of $1.9 million and net amortization and accretion on investment securities of $1.9 million. The change in operating assets and liabilities was primarily due to a $38.8 million decrease in deferred revenue, a $4.3 million decrease in accrued and other current liabilities, a $0.8 million increase in other long-term assets and a $0.3 million decrease in other long-term liabilities, offset by a $4.2 million increase in accounts payable and a $0.7 million decrease in prepaid expenses and other current assets.

Investing Activities

During the three months ended March 31, 2021, net cash used in investing activities of $96.8 million was related to cash provided by investment maturities of $268.2 million, offset by cash used in purchases of investments of $149.1 million,

cash used in the purchase of stock in equity method investment of $15.9 million and cash used in the purchase of property and equipment of $6.5 million.

Financing Activities

During the three months ended March 31, 2021, cash provided by financing activities of $6.0 million was related to $4.1 million of cash provided by the issuance of common stock upon exercise of stock options and $2.0 million of cash provided by the sale of common stock through the employee stock purchase plan.

Contractual Obligations and Commitments

For our contractual obligations and commitments as of December 31, 2020, please see “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligation and Commitments” in our Annual Report.

Commitments

Our commitments primarily consist of obligations under our agreements with Pfizer, Cellectis, Servier and Notch. Under these agreements we are required to make milestone payments upon successful completion of certain regulatory and sales milestones on a target-by-target and country-by-country basis. The payment obligations under the license agreements are contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As of March 31, 2021, 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 “—Our Research and Development and License Agreements” above.

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 March 31, 2021, the Company had non-cancellable purchase commitments of $4.1 million.

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 is expected to commence in the second quarter of 2021. 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 require the funding of specific payments, if certain events occur, such as a change of control and the termination of employment without cause.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our 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

Please refer to Note 2 to our unaudited condensed consolidated financial statements appearing under Part 1, Item 1 of this report for a discussion of new accounting standards and updates that may impact us.

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, cash equivalents and investments of $964.2 million as of March 31, 2021 consist of bank deposits, money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. A 10% change in the interest rates in effect on March 31, 2021 would not have had a material effect on the fair market value of our cash equivalents and available-for-sale securities.

Foreign Exchange Rate Risk

Our collaboration agreement with Servier requires collaboration payments for shared clinical development costs to be paid in Euros, and thus we face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. An adverse movement in foreign exchange rates could have an effect on payments due and made to our collaboration partner as well as other foreign suppliers and for license agreements. A 10% change in the applicable foreign exchange rates during the periods presented would not have had a material effect on our condensed consolidated financial statements. As of March 31, 2021, we had $4.5 million of other 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 this system occurs, we are experiencing 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 March 31, 2021 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 principal 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.
- The COVID-19 global pandemic is adversely impacting our business, including our preclinical studies and clinical trials.
- We are heavily reliant on our partners for access to key gene editing technology for the manufacturing and development of our product candidates.
- 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 could 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.
- Initial, interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- 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 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. 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 the availability of suitable donor material and other specialty raw materials, which may not be available to us on acceptable terms or at all.
- 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 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 Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2020 (Annual Report), which was filed with the SEC on February 25, 2021.

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, 2020, we reported a net loss of $250.2 million. For the quarter ended March 31, 2021, we reported a net loss of $33.0 million. As of March 31, 2021, we had an accumulated deficit of $679.4 million.

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.

Even if we succeed in 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. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. 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 and neutropenic sepsis;
- using medicines to preempt or manage adverse side effects of our product candidates, which 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 increase the risk of infections and other adverse side effects;
- obtaining regulatory approval, as the U.S. Food and Drug Administration (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.

Cellectis'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 Cellectis has generated nucleases for many specific gene sequences, it has not created nucleases for all gene sequences that we may seek to target, and Cellectis may have difficulty creating nucleases for other gene sequences that we may seek to target, which could limit the usefulness of this technology. This technology may also not be shown to be effective in clinical studies that Cellectis, we or other licensees of Cellectis technology 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. 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.

The COVID-19 global pandemic is adversely impacting our business, including our preclinical studies and clinical trials.

Public health crises such as pandemics or other outbreaks could adversely impact our business. As a result of the COVID-19 pandemic, or similar pandemics, and government response to pandemics, we have and may in the future experience disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- halting or suspending enrollment in our clinical trials;
- delays or difficulties in enrolling and retaining patients in our clinical trials;
- interruption of key clinical trial activities, such as obtaining laboratory materials for collecting patient samples, clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;

- increased adverse events and deaths in our clinical trials due to COVID-19 related infections, which may result in increased complications due to immune suppression from our lymphodepletion regimen;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or being forced to quarantine;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and investigational new drug application-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our raw materials or product candidates from our suppliers and contract manufacturing organizations (CMOs) due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems, or due to prioritization of production for COVID-19 specific therapies or vaccines; and
- limitations on employee resources that would otherwise be focused on advancing our business, including because of sickness of employees or their families, including executive officers and other key employees, the desire of employees to avoid contact with large groups of people, an increased reliance on working from home or mass transit disruptions.

State and local government response to the pandemic has included "shelter in place", "stay at home" and similar types of orders, which have limited travel and business operations in our locations, the location of our clinical trial sites, and the location of key vendors, including our CMOs. Beginning the week of March 9, 2020, the majority of our workforce began working from home. The effects of the stay-at-home orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our development programs, regulatory and commercialization timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. While we, our clinical trials sites and certain of our vendors, including our CMOs, are currently exempt from the orders for certain essential operations, any of the applicable exemptions may be curtailed or revoked, which would further adversely impact our business.

In addition, the trading prices for our common stock and other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock or such sales may be on unfavorable terms. Market and economic deterioration could also adversely impact our portfolio of corporate and government bonds.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic may impact our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, travel restrictions and actions to contain the pandemic or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease.

We are heavily reliant on our partners for access to key 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 Cellectis's TALEN gene-editing technology to inactivate a gene coding for TCRα, a key component of the natural antigen receptor of T cells, to cause the engineered T cells to be incapable of recognizing foreign antigens. Accordingly, when injected into a patient, the intent is for the engineered T cell not to recognize the tissue of the patient as foreign and thus avoid attacking the patient's tissue. In addition, we use TALEN gene editing 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 Cellectis for rights to use TALEN technology for 15 select cancer targets, including BCMA, FLT3, CD70, DLL3 and other targets included in our pipeline. We also rely on Cellectis, through our agreement with Servier, for rights to UCART19, ALLO-501 and ALLO-501A. We would need an additional license from Cellectis or access to other gene-editing technology to research and develop product candidates directed at targets not covered by our existing agreements with Cellectis and Servier. In addition, the Cellectis gene-editing technology may fail to produce viable product candidates. Moreover, both Servier and Cellectis may terminate our respective agreements in the event of a material breach of the agreements, or upon certain insolvency events. 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, particularly given the limited number of alternative gene-editing technologies in the market.

In addition, pursuant to the Servier Agreement, we expect Servier to continue to support our clinical trials of ALLO-501 and ALLO-501A for the treatment of patients with R/R NHL. Should Servier become unable to continue providing its share of financial support for the ALLO-501 and ALLO-501A clinical trials, our expenses may be greater than we currently expect and we may have difficulty progressing our ongoing and planned clinical trials in a timely manner. Moreover, as the CALM and PALL clinical trials of UCART19 have completed, we are reliant on Servier for progressing a development strategy for ALL and any development strategy may face challenges, such as regulatory delays and unforeseen expenses if we consolidate programs.

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 there can be no assurance that any development problems we 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 partners, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all. In addition, since we are in the early stages of clinical development, we do not know 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 or have off-target toxicities. Since CD70 is found on activated T cells, ALLO-316 may also cause fratricide resulting in the loss of ALLO-316 cells or increase the risk of infections. In addition, our ALLO-605 product candidate is our first TurboCAR candidate that is designed to mimic cytokine signaling selectively within CAR T cells. Our TurboCAR product candidates may be more difficult to manufacture, which could delay the initiation of our Phase 1 clinical trial of ALLO-605, or not demonstrate any of the benefits that we expect. As potentially more potent, our TurboCAR product candidates may also increase the risk of adverse events, such as CRS and neurotoxicity.

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 not experienced with autologous products. 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, including ALLO-501A and ALLO-715. Because ALLO-501, ALLO-501A and ALLO-715 are among the first allogeneic products to be evaluated in the clinic, the failure of any such product candidate, 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 regards to the viability of our entire pipeline of allogeneic T cell therapies. For instance, we are planning to progress to the Phase 2 portion of the ALPHA2 trial of ALLO-501A by the end of 2021. In order to do so, we will need to complete many objectives, such as continued enrollment in the ALPHA trial and ALPHA2 Phase 1 portion of the trial, timely patient follow-up, generation of positive Phase 1 data, advancement of cGMP manufacturing of ALLO-501A and approval from the FDA on any Phase 2 plan. If we are unable to achieve any of these objectives, we may not be able to advance to Phase 2 in a timely manner or at all, which would significantly harm our business.

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 safety or 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 could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.*

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, and adverse events have resulted in the death of patients. We expect similar adverse events for allogeneic CAR T product candidates.

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, such as to COVID-19, that may be unable to be cleared by the patient and ultimately lead to death. Our lymphodepletion regimen has caused and may also cause prolonged cytopenia. 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 cyclophosphamide, 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 serious infections, prolonged cytopenia, prolonged pancytopenia, hypokalemia, multiple organ dysfunction syndrome and neutropenic sepsis. As reported, patients have died from adverse events and future patients may also experience toxicity resulting in death. For additional safety data, please see "Business--Product Pipeline and Development Strategy" 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, our allogeneic CAR T cell product candidates undergo gene engineering by using lentivirus and TALEN nucleases that can cause insertion, deletion, or chromosomal translocation. These changes can cause allogeneic CAR T cells to proliferate uncontrollably and may cause adverse events. In addition, we may combine the use of our product candidates with other investigational therapies that may cause separate adverse events or events related to the combination. For instance, we are advancing a combination of ALLO-715 and nirogacestat, a gamma secretase inhibitor, in a cohort in the UNIVERSAL trial. The most common adverse events relating to nirogacestat in prior trials have included diarrhea, nausea, fatigue, hypophosphatemia, vomiting, rash, cough, decreased appetite, pyrexia and hypokalemia. These or other adverse events could result in the suspension of therapy or otherwise adversely impact the UNIVERSAL trial.

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. The 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 ongoing and any future 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.

Initial, interim and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish initial, interim or preliminary data from our clinical studies. Interim 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. For instance, we have published preliminary data from the ALPHA trial and UNIVERSAL trial, however such results are preliminary in nature, do not bear statistical significance 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 ongoing or future clinical trials of anti-CD19 or anti-BCMA CAR T cell product candidates or our other product candidates.

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 file 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 chemistry, manufacturing and control related topics, including product specification,

will be a focus of IND reviews, which may delay the clearance of INDs or IND amendments. For instance, we intend to optimize the manufacturing of our product candidates, including ALLO-501A, and regulatory authorities may require additional studies or clinical data to support the changes, which could delay our clinical trial timelines, including the Phase 2 portion of the ALPHA2 trial. 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 and we plan to update the IND as we finalize pivotal manufacturing of ALLO-647 at one of our CMOs. 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 study 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 or controlling a manufacturing process suitable for clinical trials;
- 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 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 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;
- transfer of manufacturing processes to any new CMO or our own manufacturing facilities 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, including due to suppliers prioritizing COVID-19 specific treatments or vaccines; 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, including due to our CMOs or other vendors prioritizing COVID-19 specific treatments or vaccines.

The COVID-19 pandemic may also increase the risk of certain of the events described above and delay our development timelines. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. 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 ongoing and planned 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. 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 who remain in the study until its conclusion. The COVID-19 pandemic, including the travel and business restrictions imposed by government authorities in response to the pandemic, have resulted in, and may continue to cause, reduced enrollment and may also create challenges to related clinical trial activities. In addition, the enrollment of patients depends 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 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 that may interact with our product candidates, which would render the patients ineligible for treatment.

In addition, prior treatment with rituximab may interfere with ALLO-501 as ALLO-501 contains rituximab recognition domains. Since rituximab is a typical part of a treatment regimen for a patient with NHL, patient eligibility for the ALLO-501 trial may be limited. Patients may also undergo plasmapheresis to remove rituximab prior to infusion of ALLO-501, which may cause separate adverse effects. We have removed the rituximab recognition domains in the second generation of ALLO-501, known as ALLO-501A, which we believe will potentially facilitate treatment of patients who were recently treated with rituximab. However, ALLO-501A may not behave as expected and may be challenging to develop or manufacture.

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.

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 and hematopoietic cell transplantation or 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. 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.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned 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 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 a transient and sometimes prolonged immune suppression that is associated with an increased risk of infection, such as to COVID-19, that may be unable to be cleared by the patient and ultimately lead to 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 are using in our clinical trials. ALLO-647 may cause serious adverse events that alemtuzumab may cause, including fatal adverse events, immune thrombocytopenia, glomerular nephropathies, thyroid disorders, autoimmune cytopenias, autoimmune hepatitis, hemophagocytic lymphohistiocytosis, acquired hemophilia and 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. See "Business--Product Pipeline and Development Strategy" 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, or if regulatory authorities do not approve the use of ALLO-647 in combination with our allogeneic T cell product candidates, we may be unable to source alemtuzumab and our engineered allogeneic T cell product candidates may be less effective, which could result in delays in our product development efforts and/or the commercial potential of our product candidates.

We intend to operate our own cell therapy manufacturing facility, which will require significant resources and we may fail to successfully operate our facility, 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 and cell processing on our own or at our CMO, including mass-producing off-the-shelf product 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. We cannot be sure that the manufacturing processes employed by us or the technologies that we incorporate for manufacturing will result in T cells that will be safe and effective.

In February 2019, we entered into a lease for approximately 118,000 square feet to develop a state-of-the-art cell therapy manufacturing facility in Newark, California. While we expect to initiate manufacturing under current good manufacturing practices (cGMP) in the second half of 2021, any business interruptions or delays to our validation or commissioning efforts, securing equipment and raw materials, or obtaining appropriate regulatory or licensing approvals, in each case which may be more likely as a result of the COVID-19 pandemic, will delay our manufacturing timelines.

Any changes in manufacturing of our product candidates currently in the clinic, including introducing product candidates manufactured at our facility into any ongoing clinical trials, will require that we meet certain regulatory conditions, such as establishing comparability with the product candidates manufactured at our CMO, and our inability to meet such conditions may result in a delay in using our manufacturing facility for production or extend our clinical trial timelines.

We also do not yet have sufficient information to reliably estimate the cost of the clinical and commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. In addition, the ultimate clinical and any commercial dose and treatment regimen will affect our ability to scale and our costs per dose. For instance, because ALLO-715 may require a higher dose than ALLO-501A, it is possible that it may be more difficult to scale ALLO-715 production to meet any demand. As a result, we may never be able to develop a commercially viable product. The commercial manufacturing facility we build will also require FDA approval, which we may never obtain. Even if approved, we would be 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.

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 scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, 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 facilities 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, our CMOs or any other of our or their 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 disputes. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients would be jeopardized.

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

We currently have no sales, marketing or distribution capabilities and as a company 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. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

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

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

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

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;

- differing standards 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; and
- business interruptions resulting from the COVID-19 pandemic or other 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 "Item 1. Business—Competition" 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 and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Executive Chair, our President and Chief Executive Officer, our Chief Financial Officer, our Executive Vice President of Research & Development and Chief Medical Officer, our Chief Technical Officer, and our General Counsel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.

We conduct substantially all of our operations at our facilities in South San Francisco. 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.

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 may be 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. 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 continue to grow the size of our organization, and we may experience difficulties in managing this growth.*

As of May 3, 2021, we had 276 full-time employees. As our development, manufacturing and commercialization plans and strategies develop, we have rapidly expanded our employee base and expect to add managerial, operational, sales, research and development, marketing, financial and other personnel. Current and 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. Our ability to build our organization and manage our employees has also been affected by the COVID-19 pandemic, as many of our staff are working from home on a part-time or full-time basis. The effects of the stay-at-home orders and our work-from-home policies may negatively impact productivity, disrupt our business and delay our development programs, regulatory and commercialization timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course.

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 new 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.

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

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

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

- unanticipated liabilities related to acquired companies or joint ventures;
- difficulties integrating acquired personnel, technologies and operations into our existing business;
- retention of key employees;
- diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges;
- increases in our expenses and reductions in our cash available for operations and other uses;
- disruption in or termination of our relationships with collaborators or suppliers as a result of such a transaction; and
- possible write-offs or impairment charges relating to acquired businesses or joint ventures.

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 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 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.

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 registration trials for multiple products in multiple regions. Further, if approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

As of March 31, 2021, we had $964.2 million in cash, 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 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.

Our internal computer systems, or those used by our CROs, collaborators or other contractors or consultants, may fail or suffer security breaches.

Our internal computer systems and those of our CROs, collaborators, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, cybersecurity threats, and telecommunication and electrical failures. In addition, the COVID-19 pandemic has intensified our dependence on information technology systems as many of our critical business activities are currently being conducted remotely. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, financial loss or otherwise compromise our confidential or proprietary information and disrupt our operations. Any failure to prevent or mitigate security breaches 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.

Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. In addition, failure to maintain effective internal accounting controls related to security breaches and cybersecurity in general could impact our ability to produce timely and accurate financial statements and subject us to regulatory scrutiny. Any failure by third-party providers to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us.

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, typhoons, fires, extreme weather conditions, medical epidemics 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 zones. The ultimate impact on us, our significant suppliers and our general infrastructure of being located near major earthquake faults and fire zones and being consolidated in certain geographical areas is unknown, but our operations and financial condition could suffer in the event of a major earthquake, fire or other natural disaster.

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.

European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

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

The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with our EU clinical trials. Failure to comply with the requirements of the 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, and other administrative penalties. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act (CPPA), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. 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.

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 legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act (Tax Act), as modified by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), 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 in tax years beginning after December 31, 2020, is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Act or the CARES Act. 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. For example, California imposed limits on the usability of California state net operating losses to offset taxable income in tax years beginning after 2019 and before 2023. 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 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. In the past, Servier was responsible for UCART19 manufacturing, and experienced UCART19 supply issues that limited its ability to recruit new patients in the past. There can be no assurance that we will not experience supply or manufacturing issues in the future.

While we are in the process of developing our own manufacturing facility for cell therapies, we must currently rely on outside vendors to manufacture supplies and process our product candidates. 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.

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.

We do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product.

In addition, our anticipated 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 CMOs may also be required to shutdown in response to the spread of COVID-19 or they may prioritize manufacturing for COVID-19 therapies or vaccines. 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. Any additional or future damage or loss of raw materials 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 will 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 donors of T cells 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 our screening process may fail to identify suitable donor material and we may discover failures 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.

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 ongoing clinical trials on the timelines we expect, which could harm our reputation and adversely impact our business and prospects.

In addition, vendors have in the past been unable to secure donor material during the COVID-19 pandemic due to government restrictions on business activity and travel. While we have donor material on hand, and our vendors are currently able to provide us with donor material, if the COVID-19 pandemic continues and 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 have curtailed their operations during the COVID-19 pandemic or focused their operations on supporting COVID-19 therapies and vaccines, and our ability to source raw materials has been impacted. Accordingly, we may experience 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, especially 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. The time and effort to qualify a new supplier, including to meet any regulatory requirements for such qualification, could result in additional costs, 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. 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. 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 biologics license application (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 the chemistry, manufacturing and controls for the product.

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 regulatory approval of future CAR-based product candidates by target, regardless of cancer type or origin, which the FDA may have difficulty accepting if our clinical trials only involved cancers of certain origins. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data 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 may also experience 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 before the product candidate is manufactured and returned to the site, 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 and delivering product candidates for use in clinical trials.

We could also encounter 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 the Data Safety Monitoring Committee. The FDA's review of our data of our ongoing 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.

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

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

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

The 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. For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. 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.

If and when our ongoing and planned Phase 1 clinical trials are completed and, assuming positive data, we expect to advance to potential registrational trials. 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 registrational trials for ALLO-501A and ALLO-715 to be designed to evaluate the efficacy of the product candidate in an open-label, non-comparative, two-stage, pivotal, multicenter, single-arm clinical trial in patients who have exhausted available treatment options. If the results are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for the relevant product candidate. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA. For example, 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.

Given the molecular similarities between ALLO-501 and ALLO-501A, we may have additional difficulties progressing any clinical trial of ALLO-501A, if emerging data from the clinical trial of ALLO-501 have safety or other issues.

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 fail to receive regulatory approval for many reasons, including the following:

- 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 our manufacturing process and inspect our commercial manufacturing facility and may not approve our manufacturing process or facility; and
- 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.

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 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, we expect regulatory authorities will require us to demonstrate the safety of ALLO-647 and its contribution to the overall benefit to risk ratio of the lymphodepletion regimen, including through a cohort of patients that do not receive ALLO-647. If we are unable to meet any of the requirements of the regulatory authorities, we may be required to conduct additional clinical studies. We cannot be certain we will be able to successfully obtain regulatory approval of ALLO-647 in a timely manner or at all. 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 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 may seek RMAT designation for additional product candidates. In 2017, the FDA established the RMAT designation to expedite review of a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates that the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. There is no assurance that we will be able to obtain RMAT designation for any of our additional product candidates. RMAT designation does 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 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.

We plan to seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. Some of our product candidates target indications that are not orphan indications. In addition, even if we obtain 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. In addition, although we may seek orphan drug designation for other product candidates, we may never receive such designations.

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. 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.

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.*

Third-party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our product candidates, if approved, profitably. In particular, in 2010 the Affordable Care Act was enacted. The Affordable Care Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state and federal government for covered outpatient drugs and certain biologics, including our product candidates, under the Medicaid drug rebate program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid drug rebate program, extended the Medicaid drug rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government’s comparative effectiveness research. Additionally, the Affordable Care Act allowed states to implement expanded eligibility criteria for Medicaid programs, imposed a new Medicare Part D coverage gap discount program, expanded the entities eligible for discounts under the Public Health Service pharmaceutical pricing program and implemented a new Patient-Centered Outcomes Research Institute. There have been legal and political challenges to certain aspects of the Affordable Care Act. The U.S. Supreme Court is currently reviewing the constitutionality of the Affordable Care Act, but it is unknown when a decision will be reached. On February 10, 2021, the Biden administration withdrew the federal government’s support for overturning the Affordable Care Act. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28,

2021, President Biden issued an executive order to initiate a special enrollment period for the purposes of obtaining health insurance coverage through the Affordable Care Act marketplace, which began February 15, 2021 and will remain open through August 15, 2021. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the Affordable Care Act and our business.

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. Further, it is possible that additional government action is taken in response to the COVID-19 pandemic.

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. 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 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.

We have an exclusive collaboration with Servier 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 Cellectis to its TALEN gene-editing technology for the development of allogeneic T cell product candidates directed against 15 different cancer antigens. Our collaboration with Servier gives us access to TALEN gene-editing technology for all product candidates under the Servier 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 composition 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 or contribute to the infringement of 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 field 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 in certain developing countries, and we cannot be certain that we or Allogene Overland 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 relating to certain CAR compositions of matter and their methods of use. 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 making 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 our 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 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 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 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 ongoing and planned clinical trials of our product candidates or any future clinical trials we or Servier may conduct, or changes in the development status of our product candidates;
- our or Servier's 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, including failure to receive regulatory approval of our product candidates;
- 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;
- 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 natural or man-made disasters, such as the COVID-19 pandemic;
- 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. We are also required to have our auditors formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 on an annual basis. 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.

We are in the process of implementing a new enterprise resource planning software as part of a plan to integrate and upgrade our systems and processes. The implementation of this new software is complex and its successful and timely implementation is not assured, requires significant capital expenditures, and can be disruptive to our business operations. Any failure to maintain or implement new or improved internal controls related to this new software implementation 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.

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 and economic 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, most recently as a result of the COVID-19 pandemic. These disruptions can result in severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates 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 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, which could directly affect our ability to attain our operating goals on schedule and on budget.

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 shareholders, 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.

Use of Proceeds from our Initial Public Offering of Common Stock

We commenced our IPO pursuant to registration statements on Form S-1 (File Nos. 333-227333 and 333-227774) that were declared or became effective on October 10, 2018 and registered an aggregate of 20,700,000 shares of our common stock for sale at a public offering price of $18.00 per share and an aggregate gross offering price of $372.6 million. On October 10, 2018, we sold 18,000,000 shares of our common stock at a public offering price of $18.00 per share for an aggregate gross offering price of $324.0 million. An additional 2,700,000 shares were sold pursuant to the underwriters' option to purchase

additional shares with a public offering price of $18.00 per share for additional gross proceeds of $48.6 million. On October 15, 2018, we completed our IPO. Goldman Sachs & Co. LLC, J.P. Morgan Securities LLC, Cowen and Company, LLC and Jefferies LLC acted as joint book-running managers for our IPO.

The underwriting discounts and commissions for the offering totaled approximately $26.1 million. We incurred additional costs of approximately $3.2 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $29.3 million. Thus, net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were approximately $343.3 million. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our IPO were held in cash and cash equivalents, primarily bank money market accounts. Through March 31, 2021, we have used $276.8 million of the net proceeds from our IPO. The net proceeds from our IPO are being used, together with our cash and cash equivalents, short-term and long-term investments, to fund continued advancement of our product pipeline, with the balance to be used to fund working capital and other general corporate purposes, which may include licensing, acquiring or investing in complementary businesses, technologies, products or assets.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit number	Description of document
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38693), filed with the SEC on October 15, 2018).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38693), filed with the SEC on October 15, 2018).
4.1	Reference is made to Exhibits 3.1 and 3.2.
4.2	Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on October 2, 2018).
4.3	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).
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document - The instance document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	The cover page from the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL.

SIGNATURES

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

Date: May 5, 2021

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

Date: May 5, 2021

By: */s/ Eric Schmidt*
Eric Schmidt, Ph.D.
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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: May 5, 2021

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

Exhibit 31.2

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: May 5, 2021

/s/ Eric Schmidt

Eric Schmidt, Ph.D.
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the quarterly report of Allogene Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2021 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: May 5, 2021

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

Date: May 5, 2021

/s/ Eric Schmidt
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.