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, 2019

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)	**(Zip Code)**

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

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 ☒

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

As of May 3, 2019, the registrant had 121,539,320 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 Balance Sheets
(Unaudited)
(In thousands, except share and per share amounts)

	March 31, 2019	December 31, 2018
Assets		(1)
Current assets:		
Cash and cash equivalents	$ 92,748	$ 92,432
Short-term investments	373,392	366,952
Prepaid expenses and other current assets	10,487	8,598
Total current assets	476,627	467,982
Long-term investments	214,588	261,966
Operating lease right-of-use asset	32,394	33,015
Property and equipment, net	20,426	8,595
Intangible assets, net	603	754
Restricted cash	4,299	1,299
Other long-term assets	432	244
Total assets	$ 749,369	$ 773,855
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 12,976	$ 12,338
Accrued and other current liabilities	14,289	17,121
Total current liabilities	27,265	29,459
Lease liability, noncurrent	34,811	34,456
Other long-term liabilities	6,065	6,776
Total liabilities	68,141	70,691
Commitments and Contingencies (Notes 6 and 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value: 10,000,000 shares authorized as of March 31, 2019 and December 31, 2018; no shares were issued and outstanding as of March 31, 2019 and December 31, 2018	—	—
Common stock, $0.001 par value: 200,000,000 shares authorized as of March 31, 2019 and December 31, 2018; 121,527,320 and 121,482,671 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	121	121
Additional paid-in capital	922,816	914,265
Accumulated deficit	(243,114)	(211,528)
Accumulated other comprehensive income	1,405	306
Total stockholders' equity	681,228	703,164
Total liabilities and stockholders' equity	$ 749,369	$ 773,855

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

(1) The balance sheet as of December 31, 2018 is derived from the audited financial statements as of that date.

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

	Three Months Ended March 31,	
	2019	**2018**
Operating expenses:		
Research and development	$ 23,403	$ —
General and administrative	13,058	2,597
Total operating expenses	36,461	2,597
Loss from operations	(36,461)	(2,597)
Interest and other income, net	4,825	—
Loss before income taxes	(31,636)	(2,597)
Benefit from income taxes	50	—
Net Loss	(31,586)	(2,597)
Other comprehensive income:		
Net unrealized gain on available-for-sale investments, net of tax	1,099	—
Net comprehensive loss	$ (30,487)	$ (2,597)
Net loss per share, basic and diluted	$ (0.32)	$ (0.10)
Weighted-average number of shares used in computing net loss per share, basic and diluted	97,315,890	26,249,993

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

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

	Common Stock		Notes Receivable from Common Stockholders	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity
	Shares	Amount					
Balance — December 31, 2018	121,482,671	$ 121	$ —	$ 914,265	$ (211,528)	$ 306	$ 703,164
Stock-based compensation	—	—	—	7,867	—	—	7,867
Employee stock purchase plan	44,649	—	—	684	—	—	684
Net loss	—	—	—	—	(31,586)	—	(31,586)
Net unrealized gain on available-for-sale investments	—	—	—	—	—	1,099	1,099
Balance — March 31, 2019	121,527,320	$ 121	$ —	$ 922,816	$ (243,114)	$ 1,405	$ 681,228

	Common Stock		Notes Receivable from Common Stockholders	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Deficit
	Shares	Amount					
Balance — December 31, 2017	26,249,993	$ 26	$ (5)	$ —	$ (23)	$ —	$ (2)
Proceeds received from common stockholders for issuance of founders' stock at inception	—	—	5	—	—	—	5
Net loss	—	—	—	—	(2,597)	—	(2,597)
Balance — March 31, 2018	26,249,993	$ 26	$ —	$ —	$ (2,620)	$ —	$ (2,594)

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

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

	Three Months Ended March 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (31,586)	$ (2,597)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Stock-based compensation	7,867	—
Amortization of other intangible assets acquired	151	—
Depreciation and amortization	544	—
Net amortization/accretion on investment securities	(1,223)	—
Non-cash rent expense	1,275	—
Deferred income taxes	(50)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,892)	5
Other long-term assets	(188)	—
Accounts payable	(348)	—
Accrued and other current liabilities	(4,095)	2,597
Other long-term liabilities	(711)	—
Net cash (used in) provided by operating activities	(30,256)	5
Cash flows from investing activities:		
Purchases of property and equipment	(10,423)	—
Proceeds from sales or maturities of investments	95,708	—
Purchase of investments	(52,397)	—
Net cash provided by investing activities	32,888	—
Cash flows from financing activities:		
Proceeds from employee stock purchase plan	684	—
Net cash provided by financing activities	684	—
Net increase in cash, cash equivalents and restricted cash	3,316	5
Cash, cash equivalents and restricted cash — beginning of period	93,731	—
Cash, cash equivalents and restricted cash — end of period	$ 97,047	$ 5
Non-cash investing and financing activities:		
Property and equipment purchase in accounts payable and accrued liabilities	$ 5,134	$ —
Supplemental disclosure:		
Cash paid for amounts included in the measurement of lease liabilities	$ 391	$ —

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

Initial Public Offering

In October 2018, the Company completed an initial public offering (IPO) of its common stock. In connection with its IPO, the Company issued and sold 20,700,000 shares of its common stock, which included 2,700,000 shares of its common stock issued pursuant to the over-allotment option granted to the underwriters, at a price to the public of $18.00 per share. As a result of the IPO, the Company received approximately $343.0 million in net proceeds, after deducting underwriting discounts and commissions of $26.1 million and offering expenses of approximately $3.2 million payable by the Company. At the closing of the IPO, all 11,743,987 shares of outstanding convertible preferred stock were automatically converted into 61,655,922 shares of common stock and our outstanding convertible promissory notes in $120.2 million principal amount were automatically converted into 7,856,176 shares of common stock. Following the IPO, there were no shares of convertible preferred stock or preferred stock outstanding.

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. The Company had cash and cash equivalents and investments of $680.7 million as of March 31, 2019. Since inception through March 31, 2019, the Company has incurred cumulative net losses of $243.1 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 financial statements are filed with the Securities and Exchange Commission (SEC).

Forward Stock Split

On October 1, 2018, the Company filed an amendment to the Company's amended and restated certificate of incorporation to effect a forward split of shares of the Company's common stock on a 1-for-5.25 basis (the Forward Stock Split). In connection with the Forward Stock Split, the conversion ratio for the Company's then-outstanding convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was increased in proportion to the Forward Stock Split. The par value of the common stock was not adjusted as a result of the Forward Stock Split. All references to common stock, options to purchase common stock, early exercised options, share data, per share data, convertible preferred stock (to the extent presented on an as-converted to common stock basis) and related information contained in these condensed financial statements have been retrospectively adjusted to reflect the effect of the Forward Stock Split for all periods presented.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed 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 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 balance sheet as of March 31, 2019, the condensed statements of operations and comprehensive loss for the three months ended March 31, 2019 and 2018, the condensed statements of stockholders' equity (deficit) as of March 31, 2019 and 2018, the condensed statements of cash flows for the three months ended March 31, 2019 and 2018, and the financial data and other financial information disclosed in the notes to the condensed financial statements are unaudited. The results of operations for the three months ended March 31, 2019 are not necessarily indicative of the results to be expected for the year ending December 31, 2019, or for any other future annual or interim period. These condensed financial statements should be read in conjunction with the Company's audited financial statements and related notes for the year ended December 31, 2018, included in the Company's Annual Report on Form 10-K filed with the SEC on March 8, 2019.

Use of Estimates

The preparation of 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 financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying financial statements include but are not limited to the fair value of common stock, the fair value of stock options, the fair value of convertible notes payable, 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, 2019, as compared to the significant accounting policies described in Note 1 of the "Notes to Financial Statements" in the Company's audited financial statements included in its Annual Report.

Recently Adopted Accounting Pronouncements

In February 2018, the FASB issued Accounting Standards Update No. 2018-02, *Income Statement – Reporting Comprehensive Income (Topic 220): Reclassification of Certain Tax Effects from Accumulated Other Comprehensive Income*, which provided amended guidance to allow a reclassification from accumulated other comprehensive income to retained earnings for stranded tax effects resulting from the Tax Cuts and Jobs Act. Additionally, under the new guidance, an entity will be required to provide certain disclosures regarding stranded tax effects. The guidance is effective for fiscal years beginning after December 15, 2018, with early adoption permitted. The Company adopted this guidance on January 1, 2019.

Recent Accounting Pronouncements Not Yet Adopted

In August 2018, the FASB issued Accounting Standards Update No. 2018-15, *Intangibles – Goodwill and other – Internal-Use Software (Subtopic 350-40)*, which amended its guidance for costs of implementing a cloud computing service arrangement and aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. This new standard also requires customers to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. The guidance is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company is evaluating the impact of adopting this amendment to its 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.

There were no Level 3 assets or liabilities at March 31, 2019.

Financial assets and liabilities 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, 2019, are presented in the following tables:

	March 31, 2019			
	Level 1	Level 2	Level 3	Fair Value
	(in thousands)			
Financial Assets:				
Money market funds (1)	$ 17,162	$ —	$ —	$ 17,162
Commercial paper	—	4,952	—	4,952
Corporate bonds	—	246,697	—	246,697
U.S. treasury securities	284,893	—	—	284,893
U.S. agency securities	—	55,238	—	55,238
Total financial assets	$ 302,055	$ 306,887	$ —	$ 608,942

	December 31, 2018			
	Level 1	Level 2	Level 3	Fair Value
	(in thousands)			
Financial Assets:				
Money market funds (1)	$ 61,023	$ —	$ —	$ 61,023
Commercial paper	—	4,917	—	4,917
Corporate bonds	—	244,076	—	244,076
U.S. treasury securities	342,001	—	—	342,001
U.S. agency securities	—	62,115	—	62,115
Total financial assets	$ 403,024	$ 311,108	$ —	$ 714,132

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

There were no transfers between Levels 1, 2 or 3 for the period presented.

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, 2019 are presented in the following table:

	March 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 17,162	$ —	$ —	$ 17,162
Commercial paper	4,952	—	—	4,952
Corporate bonds	245,892	827	(22)	246,697
U.S. treasury securities	284,335	560	(2)	284,893
U.S. agency securities	55,029	209	—	55,238
Total cash equivalents and investments	$ 607,370	$ 1,596	$ (24)	$ 608,942
Classified as:				
Cash equivalents				$ 20,962
Short-term investments				373,392
Long-term investments				214,588
Total cash equivalents and investments				$ 608,942

	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
	(in thousands)			
Money market funds	$ 61,023	$ —	$ —	$ 61,023
Commercial paper	4,917	—	—	4,917
Corporate bonds	244,136	220	(280)	244,076
U.S. treasury securities	341,696	342	(37)	342,001
U.S. agency securities	61,937	181	(3)	62,115
Total cash equivalents and investments	$ 713,709	$ 743	$ (320)	$ 714,132
Classified as:				
Cash equivalents				$ 85,214
Short-term investments				366,952
Long-term investments				261,966
Total cash equivalents and investments				$ 714,132

As of March 31, 2019, the remaining contractual maturities of available-for-sale securities were less than three years. There have been no significant realized losses on available-for-sale securities for the period presented. Based on the Company's review of its available-for-sale securities, the Company believes it had no other-than-temporary impairments on these securities as of March 31, 2019, because the Company does not intend to sell these securities nor does the Company believe that it will be required to sell these securities before the recovery of their amortized cost basis. Gross realized gains and gross realized losses were immaterial for the three months ended March 31, 2019.

5. Balance Sheets Components

Prepaid expenses and Other Current Assets

Prepaid expenses and Other Current Assets consist of the following:

	March 31, 2019	December 31, 2018
	(In thousands)	
Prepaid research and development expenses	$ 4,183	$ 2,356
Accrued interest on investments	3,391	3,108
Prepaid insurance	1,629	2,376
Other prepaid and current assets	1,284	758
Total prepaid expenses and other current assets	$ 10,487	$ 8,598

Property and Equipment

Property and Equipment consist of the following:

	March 31, 2019	December 31, 2018
	(In thousands)	
Laboratory equipment	$ 7,417	$ 5,534
Leasehold improvements	127	15
Computers equipment and purchased software	1,962	1,327
Furniture and fixtures	799	64
Construction in progress	11,713	2,703
Total	22,018	9,643
Less: accumulated depreciation	(1,592)	(1,048)
Total property and equipment, net	$ 20,426	$ 8,595

Accrued Liabilities

Accrued liabilities consist of the following:

	March 31, 2019	December 31, 2018
	(In thousands)	
Unvested shares liabilities	$ 5,300	$ 4,590
Accrued research and development expenses	4,872	7,808
Accrued compensation and related benefits	2,719	4,111
Other	1,398	612
Total accrued and other current liabilities	$ 14,289	$ 17,121

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. No such payments were made in the three-months ended March 31, 2019.

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 our 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. The Company expects to pay Cellectis $5.0 million upon the dosing of the first patient in its Phase 1 clinical trial of ALLO-715. 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, 2019, no material costs have been incurred associated with research services performed by Cellectis. As of March 31, 2019, no material amount was recorded in the accrued and other current liabilities in the accompanying condensed balance sheet.

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 products, including other anti-CD19 product candidates.

Under the Servier Agreement, the Company has an exclusive license to develop, manufacture and commercialize UCART19 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 generally not required to make any additional payments to Servier to exercise an option, except for products directed at a certain target, for which the Company is required to pay Servier an option fee in the low tens of millions of dollars range upon exercise. 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 and ALLO-501, 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 on a target-by-target basis. For products directed against CD19, including UCART19, 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. The total potential payments that the Company is obligated to make under the Servier Agreement upon successful completion of regulatory and sales milestones are $381.5 million, including the CD19-related milestone payments described above. 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 million and €70.5 million ($79.1 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, 2019, the Company recorded $0.7 million of costs incurred under the cost-sharing terms of the Servier Agreement as research and development expenses. As of March 31, 2019, amounts due to Servier of $2.2 million was recorded in the accounts payable and $1.0 million in accrued and other current liabilities in the accompanying condensed balance sheet.

7. 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 the right to make tenant improvements, including the addition of laboratory space, with a lease incentive allowance of $5.1 million. The rent payments began on March 1, 2019 after an abatement period. In connection with the lease, the Company has maintained a letter of credit for the benefit of the landlord in the amount of $1.0 million. In connection with this lease, the Company recognized an operating lease right-of-use asset of $24.2 million as of March 31, 2019 and an aggregate lease liability of $26.7 million in the accompanying condensed balance sheet. The remaining lease term is 9 years and 11 months, and the estimated incremental borrowing rate is 8.0%.

In October 2018, the Company entered into an operating lease agreement for new office and laboratory space which consists of approximately 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 the right to make 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 connection with the lease, the Company has maintained a letter of credit for the benefit of the landlord in the amount of $0.2 million. In connection with this lease, the Company recognized an operating lease right-of-use asset of $6.1 million as of March 31, 2019 and an aggregate lease liability of $6.3 million in the accompanying balance sheet. The remaining lease term is 9 years and 11 months, and the estimated incremental borrowing rate is 8.0%.

In December 2018, the Company entered into two operating leases for office space in New York and Los Angeles for approximately 4,358 and 1,293 square feet respectively. The Company recognized operating lease right-of-use assets of $1.9 million and $0.2 million as of March 31, 2019 and aggregate lease liabilities of $1.9 million and $0.2 million respectively for these leases. The lease term for the New York operating lease is 6 years and 7 months, with no option for renewal. The lease term for the Los Angeles operating lease is 3 years with an option to extend the lease term for another two years which is not reasonably certain of exercise. There were no lease incentive allowances for either location. In connection with the New York lease, the Company maintains a letter of credit for the benefit of the landlord in the amount of $0.1 million. The remaining lease terms were 6 years and 3 months and 2 years and 8 months at March 31, 2019 and the estimated incremental borrowing rates applied were 8% and 7%, respectively.

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 15 years and 8 months and is expected to commence in May 2020. Upon certain conditions, the Company has two ten-year options to extend the lease. Subject to rent abatement for the second through nine months of the lease, the Company will be required to pay $159,150 per month for rent for the first twelve months of the lease term which will increase at a rate of 3% per year. The Company will be entitled to a tenant improvement allowance of $2.9 million for costs related to the design and construction of certain Company improvements. In connection with the lease, the Company maintains a letter of credit for the benefit of the landlord in the amount of $3.0 million. The total commitment of undiscounted lease payments for this lease was $36.2 million as at March 31, 2019. The Company has not recognized a right-of-use asset or aggregate lease liability as of March 31, 2019 as the underlying asset was unavailable for use by the Company at any time in the period ended March 31, 2019.

The undiscounted future lease payments under the lease liabilities as of March 31, 2019 were as follows:

Year ending December 31:	**(in thousands)**
2019 (remaining 9 months)	$ 3,168
2020	5,971
2021	7,792
2022	7,958
2023	8,213
2024 and thereafter	63,517
Total undiscounted lease payments	96,619
Less: Undiscounted lease payments related to Newark lease	(36,231)
Less: Present value adjustment	(19,333)
Less: Tenant improvement allowance	(5,942)
Total	$ 35,113

Rent expense for all operating leases was $1.4 million for the three months ended March 31, 2019. Short-term lease expense was $1.0 million for the three months ended March 31, 2019. Variable lease payments for operating expenses was $0.3 million for the three months ended March 31, 2019. There was a total commitment of $0.7 million at March 31, 2019 related to short-term leases.

8. Stock-Based Compensation

In June 2018, the Company adopted the 2018 Equity Incentive Plan (2018 Plan). The 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 October 2018, the Board of Directors approved an amendment and restatement of the 2018 Plan, increasing the shares of common stock issuable under the 2018 Plan as well as allowing for an automatic annual increase to the shares issuance under the 2018 Plan to the amount equal to 5% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. The term of any stock option granted under the 2018 Plan cannot exceed 10 years. The Company generally grants stock-based awards with service conditions only. Options granted typically vest over a four-year period but may be granted with different vesting terms. 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, 2019, there were 12,546,247 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:

	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term (In years)
Balance, December 31, 2018	7,235,545	$ 7.72	9.62
Options granted	1,834,111	27.29	9.94
Options exercised	—	—	—
Options forfeited	(130,100)	4.60	9.28
Balance, March 31, 2019	8,939,556	$ 11.78	9.49
Exercisable, March 31, 2019	3,692,378	$ 10.02	9.48
Vested and expected to vest, March 31, 2019	8,939,556	$ 11.78	9.49

Restricted Stock Unit Activity

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

	Restricted Stock Units	Weighted-Average Fair Value at Date of Grant per Share
Unvested at December 31, 2018	—	—
Granted	1,102,028	$ 27.29
Vested	—	—
Forfeited	—	—
Unvested at March 31, 2019	1,102,028	$ 27.29
Vested and expected to vest, March 31, 2019	1,102,028	$ 27.29

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:

	Three Months Ended March 31, 2019 (In thousands)
Research and development	$ 2,732
General and administrative	5,135
Total stock-based compensation	$ 7,867

Early Exercised Options

The Company allows certain of its employees and its directors to exercise options granted under the 2018 Plan prior to vesting. The shares related to early exercised stock options are subject to the Company's lapsing repurchase right upon termination of employment or service on the Company's board of directors at the lesser of the original purchase price or fair market value at the time of repurchase. In order to vest, the holders are required to provide continued service to the Company. The proceeds are initially recorded in accrued and other liabilities and other long-term liabilities for the noncurrent portion. The proceeds are reclassified to paid-in capital as the repurchase right lapses. As of March 31, 2019, there was $5.3 million recorded in accrued and other liabilities and $6.1 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 financial statements since the exercise date.

9. Related Party Transactions

As of March 31, 2019, Pfizer held 22,032,040 shares of Common Stock and had appointed one member to the Company's board of directors.

In April 2018, the Company and Pfizer entered into a transition services agreement (the Pfizer TSA) for Pfizer to provide professional services to the Company related to research and development, project management, and other administrative functions. For the three months ended March 31, 2019, the costs incurred under the Pfizer TSA were $2.7 million.

The Company also purchased certain lab supplies from Pfizer in connection with its research and development activities. For the three months ended March 31, 2019, the total lab supplies and services purchased from Pfizer was $0.6 million.

As of March 31, 2019, the Company had an amount payable to Pfizer of $1.7 million, which was recorded in the accrued and other current liabilities on the accompanying condensed balance sheets.

Sublease Agreement

In February 2019, the Company subleased approximately 2,180 square feet of its office space in New York, New York, to ByHeart, Inc., formerly known as Second Science, Inc. (ByHeart). ByHeart is a development stage infant formula company. Two of the Company's board members have beneficial ownership in ByHeart and one serves on the board of directors of ByHeart. Sublease income for the three months ended March 31, 2019 was $0.1 million and was recognized as other income.

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 was $0.2 million for the three months ended March 31, 2019.

In August 2018, the Company entered into a consulting agreement with Bellco Capital LLC (Bellco). The Company's executive chairman, Arie Belldegrun, M.D., FACS, is the Chairman and an owner of 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 pays Bellco $33,333.33 per month in arrears commencing January 2019 and, in the Company's discretion, may 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 for the three months ended March 31, 2019.

10. Income Taxes

The Company has a history of losses, and expects to record a loss in 2019. The Company continues to maintain a full valuation allowance against its net deferred tax assets.

11. 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:

	Three Months Ended March 31,	
	2019	**2018**
Stock options to purchase common stock	8,939,556	—
Restricted stock units subject to vesting	1,102,028	—
Expected shares purchased under Employee Stock Purchase Plan	265,455	—
Founder shares of common stock subject to future vesting	18,173,066	—
Early exercised stock options subject to future vesting	5,020,580	—
Total	33,500,685	—

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 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, 2018 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, 2018 (Annual Report), which was filed with the Securities and Exchange Commission (SEC) on March 8, 2019. 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 CAR T cell product candidates targeting multiple promising antigens in a host of hematological malignancies and solid tumors. In collaboration with Servier, we are developing UCART19 and ALLO-501, chimeric antigen receptor (CAR) T cell product candidates targeting CD19. Servier is sponsoring two Phase 1 clinical trials of UCART19 in patients with relapsed/refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL), one for adult patients (the CALM trial) and one for pediatric patients (the PALL trial). Servier is also responsible for manufacturing UCART19 and previously experienced UCART19 supply issues that limited its ability to recruit new patients. Servier is currently in the process of advancing its supply and re-initiating recruitment for the CALM and PALL trials. We continue to expect UCART19 to be advanced to potential registrational trials in 2020.

We are sponsoring a Phase 1/2 clinical trial (the ALPHA trial) of ALLO-501 in patients with R/R non-Hodgkin lymphoma (NHL). In January 2019, the U.S. Food and Drug Administration (FDA) cleared our investigational new drug application (IND) and we have opened enrollment in the ALPHA trial at multiple clinical trial sites. We are responsible for manufacturing ALLO-501 and do not believe the UCART19 supply issues will affect our manufacturing of ALLO-501. We expect to report initial data from the Phase 1 portion of the trial in the first half of 2020. We plan to introduce our second-generation version of ALLO-501 prior to the start of the Phase 2 portion of the ALPHA trial. We have removed rituximab recognition domains in the second-generation version of ALLO-501, which we believe will potentially facilitate treatment of patients who were recently treated with rituximab.

In addition, we have submitted an IND to initiate a Phase 1 clinical trial of ALLO-715, an allogeneic CAR T cell product candidate targeting B-cell maturation antigen (BCMA) in patients with R/R multiple myeloma. 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. Subject to IND clearance, we remain on track to initiate the Phase 1 trial in 2019.

Since inception, we have had significant operating losses. Our net loss was $31.6 million for the three months ended March 31, 2019. As of March 31, 2019, we had an accumulated deficit of $243.1 million. As of March 31, 2019, we had $680.7 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, general and administrative expenses, and capital expenditures will continue to increase.

Our Research Development and License Agreements

Research Collaboration and License Agreement with Cellectis

In June 2014, Pfizer entered into a Research Collaboration and License Agreement (the Original Cellectis Agreement) with Cellectis S.A. (Cellectis). In April 2018, Pfizer assigned the agreement to us pursuant to the Pfizer Agreement.

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, 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.

The material rights and obligations of the parties under the Cellectis Agreement are otherwise consistent with the material rights and obligations of the parties under the Original Cellectis Agreement. See Note 6 to our condensed financial statements included elsewhere in this report for further description of the Cellectis Agreement.

Exclusive License and Collaboration Agreement With Servier

In October 2015, Pfizer entered into an Exclusive License and Collaboration Agreement (Servier Agreement) with Servier to develop, manufacture and commercialize certain allogeneic anti-CD19 CAR products, including UCART19, in the United States with the option to obtain the rights over additional products, including other allogeneic anti-CD19 CAR product candidates. In April 2018, Pfizer assigned the agreement to us pursuant to the Pfizer Agreement. See Note 6 to our condensed financial statements included elsewhere in this report for further description of the Servier Agreement.

Transition Services Agreement

In connection with the closing of the Pfizer Agreement, we entered into a Transition Services Agreement (TSA) with Pfizer in April 2018, pursuant to which Pfizer provides us with certain (i) research and development services, including services relating to testing, studies, and clinical trials, project management services, laboratory equipment and operations services, animal care services, data storage services and regulatory strategy services, and (ii) general and administrative services, including business technology services, compliance services, finance/accounting services, and procurement, manufacturing and supply chain services, with respect to the assets that we purchased from Pfizer. Under the TSA, Pfizer also provides us with certain facilities and facility management services. The services are provided by certain employees of Pfizer as independent contractors of Allogene. We believe that it is helpful for Pfizer to provide such services to us under the TSA to help facilitate the efficient operation of our business after the asset purchase.

Pfizer began providing the services in May 2018 and has been continually providing services during the three months ended March 31, 2019. We plan to transition from Pfizer services and facilities throughout 2019. The services and employees for each service may be amended from time to time by the parties.

The TSA provides that Pfizer will indemnify us for damages that result from Pfizer's gross negligence, willful misconduct or material breach of the TSA and that we will indemnify Pfizer for damages that arise from the provision of the services, unless such damages result from Pfizer's gross negligence, willful misconduct or material breach. We are also required to indemnify Pfizer for damages that arise from our material breach of the TSA.

The term of the agreement began in April 2018 and ends on the earlier to occur of the last date that Pfizer is required to provide the services or the termination of the TSA in accordance with the agreement. Either party may terminate the agreement upon 60 days' prior written notice in the event of the other party's uncured material breach. Pfizer may terminate the TSA upon 10 days' prior written notice in the event of our non-payment, if left uncured. We may terminate our use of the facilities with 60 days' written notice.

Components of Results of Operations

Operating Expenses

Research and Development

To date, our research and development expenses have related primarily to discovery efforts and preclinical and clinical development of our product candidates. Research and development expenses that were incurred for the three months ended March 31, 2019 related to development of pipeline product candidates UCART19, ALLO-501 and ALLO-715. The most significant research and development expenses for the quarter relates to the following costs incurred for the development of our product candidates, UCART19, ALLO-501 and ALLO-715, which include:

- expenses incurred under agreements with our collaboration partner 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 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; and
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies.

Other significant research and development costs include costs relating to facilities and overhead costs, including payments to Pfizer under the TSA for use of their facilities. 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 development of UCART19, including for the CALM and PALL clinical trials. 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, including for the ALPHA clinical trial. Collaboration expenses and cost reimbursement is recorded on a net basis as a research and development expense in our 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 over the next several years as our UCART19, ALLO-501 and ALLO-715 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 the case of UCART19, we are also dependent on Servier's ability to manage the CALM and PALL clinical trials. In addition, the probability of success for each product candidate will depend on numerous factors, including 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 and modification of shares of common stock issued to our founders to include vesting conditions, for personnel in executive, finance, accounting, legal, investor relations, facilities, business development, information technology and human resources functions. Other significant costs include costs relating to facilities and overhead costs, including payments to Pfizer under the TSA for use of their facilities, 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. 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 equivalents and investment gains and losses recognized during the period.

Results of Operations

Three Months Ended March 31, 2019

Our principal operations commenced in April 2018 when we acquired certain assets from Pfizer and completed a Series A and A-1 preferred stock financing. For the three months ended March 31, 2018, we incurred $2.6 million of general and administrative costs related to the foregoing activities and other start-up activities. Due to our limited operations in this period, the following discussion does not contain a comparison of the results of operations for the three months ended March 31, 2018.

The following sets forth our results of operations for the three months ended March 31, 2019 (in thousands):

	Three Months Ended March 31, 2019
Operating expenses:	
Research and development	$ 23,403
General and administrative	13,058
Total operating expenses	36,461
Loss from operations	(36,461)
Interest and other income, net	4,825
Loss before income taxes	(31,636)
Benefit from income taxes	50
Net Loss	$ (31,586)

Research and Development Expenses

Research and development expenses were $23.4 million for the three months ended March 31, 2019. Research and development expenses consisted primarily of $9.6 million in personnel-related costs, of which $2.7 million is stock-based compensation expense, $8.1 million in external costs related to our clinical programs UCART19, ALLO-501 and ALLO-715, $3.5 million in allocated building rent, facilities and information technology costs and $1.8 million for direct purchases from Pfizer and expenses incurred under the TSA.

General and Administrative Expenses

General and administrative expenses were $13.1 million for the three months ended March 31, 2019. General and administrative expenses consisted primarily of $8.5 million in personnel-related costs, of which $5.1 million is stock-based compensation expense, $2.3 million in advisory costs including legal fees, insurance fees and professional consulting service fees and $1.8 million for expenses incurred under the TSA.

Interest and Other Income, Net

Interest and other income, net was $4.8 million for the three months ended March 31, 2019 and consists primarily of interest earned on our cash equivalents and investments during the period.

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, 2019, we had $680.7 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.

In connection with our IPO, 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 $343.0 million in net proceeds. At the closing of the IPO, our outstanding convertible promissory notes in $120.2 million principal amount were automatically converted into 7,856,176 shares of common stock.

Capital Resources

Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures related to UCART19, ALLO-501 and ALLO-715, and 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 period indicated:

	Three Months Ended March 31, 2019 (In thousands)
Net cash (used in) provided by:	
Operating activities	$ (30,256)
Investing activities	32,888
Financing activities	684
Net increase in cash, cash equivalents and restricted cash	$ 3,316

Operating Activities

During the three months ended March 31, 2019, cash used in operating activities of $30.3 million was primarily attributable to a net loss of $31.6 million partially offset by non-cash charges of $8.6 million. In addition, there was a cash outflow of $7.2 million due to a net increase in operating assets. The net increase in operating assets was primarily due to an increase in prepaid expenses and other current assets of $1.9 million and a decrease in accrued liabilities of $4.1 million.

Investing Activities

During the three months ended March 31, 2019, cash provided by investing activities of $32.9 million was related to investment maturities of $95.7 million offset by purchases of investments of $52.4 million and purchases of property and equipment of $10.4 million.

Financing Activities

During the three months ended March 31, 2019, cash provided by financing activities of $0.7 million was related to net proceeds from the purchase of common stock through the employee stock purchase program.

Contractual Obligations and Commitments

For our contractual obligations and commitments as of December 31, 2018, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations" in our Annual Report. In the three months ended March 31, 2019, we 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 15 years and 8 months and is expected to commence in May 2020. Upon certain conditions, we have two ten-year options to extend the lease. Subject to rent abatement for the second through nine months of the lease, we will be required to pay $159,150 per month for rent for the first twelve months of the lease term which will increase at a rate of 3% per year.

Commitments

Our commitments primarily consist of obligations under our agreements with Pfizer, Cellectis and Servier. 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, 2019, 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 Development and License Agreements" above.

Additionally, we have entered into an agreement 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.

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 financial statements, which have been prepared in accordance with United States generally accepted accounting principles. The preparation of these 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 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 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 financial statements appearing under Part 1, Item 1 of this report for a discussion of new accounting standards 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 $680.7 million as of March 31, 2019, 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, 2019 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 foreign currency, 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 foreign exchange rates during the periods presented would not have had a material effect on our condensed financial statements. As of March 31, 2019, we had $3.2 million of liabilities denominated in foreign currencies.

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

An evaluation was also performed under the supervision and with the participation of our management, including our principal executive officer and our principal financial and accounting officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any changes in our internal control over financial reporting during the quarter ended March 31, 2019 that have materially affected, or are 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 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, 2018 (Annual Report), which was filed with the Securities and Exchange Commission (SEC) on March 8, 2019.

Risks Related to Our Business and Industry

We have a limited operating history and face significant challenges and expense as we build our capabilities.

We were incorporated in 2017 and acquired certain rights to UCART19 and other allogeneic CAR T cell therapy assets from Pfizer in April 2018. We have a limited operating history and are subject to the risks inherent in any newly-formed organization, including, among other things, risks that we may not be able to hire sufficient qualified personnel and establish operating controls and procedures. We are in the process of moving in-house several support services provided by Pfizer through a Transition Services Agreement (TSA), including certain research and development and general and administrative services. As we build our own capabilities, we expect to encounter risks and uncertainties frequently experienced by growing companies in new and rapidly evolving fields, including the risks and uncertainties described herein. Our ability to rely on services from Pfizer is limited for a period of time, and if we are unable to transition support services in a timely manner, our operating and financial results could differ materially from our expectations, and our business could suffer.

As a company, we have not progressed any product candidates through clinical development to commercialization. Our collaboration partner, Servier, conducts the CALM and PALL clinical trials of UCART19, and we cannot be certain that our planned clinical trials of our other product candidates will begin or be completed on time, if at all.

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 have only recently acquired rights to 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, 2018, we reported a net loss of $211.5 million. For the quarter ended March 31, 2019, we reported a net loss of $31.6 million. As of March 31, 2019, we had an accumulated deficit of $243.1 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, including UCART19, ALLO-501 and ALLO-715. 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;
- 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 manage adverse side effects of our product candidates which may not adequately control the side effects and/or may have 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 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.

The gene-editing technology we use is relatively new, 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 we may not be able do so, 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 and a DNA translocation that may lead to oncogenesis. The gene-editing of our product candidates may also not be successful in limiting the risk of GvHD or rejection by the patient.

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

We are heavily reliant on our partners for access to key gene editing technology for manufacturing our product candidates and for the development of UCART19 and ALLO-501.

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.

We rely on an agreement with Cellectis for rights to use TALEN and electroporation 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 potentially one additional target. 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, under the Servier Agreement, Servier is responsible for conducting the two clinical trials of UCART19, CALM and PALL. We plan to support Servier in advancing the CALM and PALL trials, and we expect Servier to support us as we initiate our clinical trial of ALLO-501 for the treatment of patients with R/R NHL. Other than the agreed-upon global research and development plan for UCART19, we have limited control over the nature or timing of Servier's clinical trials and limited visibility into their day-to-day activities. In addition, we rely on Servier for access to data from the UCART19 trials, and as a result at any given time we may not be aware of one or more significant trial developments. If UCART19 encounters safety or efficacy problems, manufacturing problems, developmental delays, regulatory issues or other problems, our development plans and business would be significantly harmed. Additionally, other clinical trials being conducted by Servier may at times receive higher priority than research on our programs. Moreover, if Servier does not provide its share of support for the UCART19 and ALLO-501 clinical trials, our expenses may be greater than we currently expect and we may have difficulty progressing ALLO-501 in a timely manner.

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 and development 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 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.

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. 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. 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 UCART19 and ALLO-501. If we or Servier are unable to obtain approval for UCART19 and ALLO-501 and effectively commercialize UCART19 and ALLO-501 for the treatment of patients in approved indications, our business would be significantly harmed.*

Our business and future success depends on our ability to obtain regulatory approval of, and then successfully commercialize, our most advanced product candidates, UCART19 and ALLO-501. UCART19 is in the early stages of development and has only been administered in a limited number of patients in Phase 1 clinical trials. The results to date may not predict results for our planned trial or any future studies of UCART19 or any other allogeneic CAR T product candidate. Because UCART19 and ALLO-501 are among the first allogeneic products to be evaluated in the clinic, the failure of either product candidate, or the failure of other allogeneic T cell therapies, may significantly influence physicians' and regulators' opinions in regards to the viability of our entire pipeline of allogeneic T cell therapies, particularly if high or uncontrolled rates of GvHD are observed. If significant GvHD events are observed with the administration of UCART19 or ALLO-501, or if either product candidate is viewed as less safe or effective than autologous therapies, our ability to develop other allogeneic therapies may be significantly harmed.

We are also dependent on Servier to oversee the manufacturing of UCART19 and conduct the UCART19 trials in a timely and appropriate manner. Servier has experienced UCART19 supply issues that limited its ability to recruit new patients. Significant delays in enrollment, due to supply issues or results from the CALM and PALL studies or other reasons, could affect the progress and success of the CALM and PALL clinical trials, our leadership position in the allogeneic CAR T industry and the ability to progress additional product candidates. In addition, we expect Servier to submit a revised pediatric investigation plan for UCART19 to the EMA in 2019. The EMA could reject the revised pediatric investigation plan, which would affect Servier's ability to progress the PALL2 clinical trial on the timeframe currently anticipated or at all.

All of our product candidates, including UCART19 and ALLO-501, 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 UCART19 and ALLO-501 are our most advanced product candidates, and because our other product candidates are based on similar technology, if either product candidate 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 and neurotoxicity, 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 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, our allogeneic CAR T cell product candidates may cause unique adverse events related to the differences between the donor and patients, such as GvHD or infusion reaction.

In the PALL and CALM clinical trials, the most common severe or life threatening adverse events resulted from CRS, prolonged cytopenia and neutropenic sepsis. Multiple patients have also died in these trials, including two deaths that were attributed to UCART19, as further described in our Annual Report under the heading "Business—Product Pipeline and Development Strategy—UCART19—Clinical Data". In the future, patients may experience additional adverse events related to the lymphodepletion regimen as well as UCART19, some of which may result in death. As we treat more patients with UCART19 in our clinical trials, new less common side effects may also emerge.

As an anti-CD19 CAR T cell therapy, we expect ALLO-501 to cause similar toxicities as UCART19. Other of our allogeneic CAR T product candidates may also cause similar or worse toxicities. For instance, because ALLO-715 may require a higher dose than UCART19 and could be used in a more elderly patient population, it is possible that the risk of GvHD or other adverse events for ALLO-715 could be greater than UCART19.

If unacceptable toxicities arise in the development of our product candidates, we or Servier 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, including UCART19, ALLO-501 and ALLO-715, 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.

Interim "top line" 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 interim "top line" 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 and Servier have published preliminary data from the CALM and PALL clinical trials, 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 UCART19 or our other product candidates.

Preliminary or "top line" 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, 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 recently submitted an IND to the FDA to initiate a clinical trial of ALLO-715 targeting BCMA for the treatment of patients with R/R multiple myeloma, and 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. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

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 these 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 advanced 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 contract manufacturing organization (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; 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.

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 clinical trials of UCART19 and ALLO-501 and in our planned clinical trials of other product candidates, we and Servier 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 UCART19 or ALLO-501, 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 UCART19 or ALLO-501 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 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; 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.

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 plan to introduce our second-generation version of ALLO-501 in the ALPHA trial. We have removed the rituximab recognition domains in the second generation of ALLO-501, which we believe will potentially facilitate treatment of patients who were recently treated with rituximab. However, we may have difficultly manufacturing or otherwise advancing the second generation of ALLO-501.

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. 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.

Clinical trials are expensive, time-consuming and difficult to design and implement.

Human clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. 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, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, costs to treat patients with R/R cancer and to treat potential side effects that may result from our product candidates can be significant. We also have less control of costs incurred by our development partner, Servier, for the clinical trials of UCART19. Accordingly, our clinical trial costs are likely to be significantly higher than for more conventional therapeutic technologies or drug products.

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 people who have the cancers we are targeting, as well as the subset of people 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 our most advanced product candidate, UCART19, to initially target a small patient population that suffers from R/R ALL. 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.

If we fail to develop additional product candidates, our commercial opportunity will be limited.

One of our core strategies is to pursue clinical development of additional product candidates beyond UCART19, including ALLO-501 and ALLO-715. Developing, obtaining regulatory approval and commercializing additional CAR T cell product candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

Even if we receive FDA approval to market additional product candidates for the treatment of cancer, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate.

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 plan to utilize an anti-CD52 monoclonal antibody as part of a lymphodepletion regimen to be infused prior to infusing our product candidates, such as UCART19, ALLO-501 and ALLO-715. 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.

In the ongoing CALM and PALL trials, we use a commercially available monoclonal antibody, alemtuzumab, that binds CD52. Alemtuzumab is known to have risk of causing certain adverse events. The EMA recently started a review of alemtuzamab in the context of the treatment of multiple sclerosis following new reports of immune-mediated conditions and problems affecting the heart and blood vessels, including fatal cases. If the EMA limits the use of alemtuzamab 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. We plan to use ALLO-647 in our clinical trial of ALLO-501 and, subject to regulatory acceptance, our clinical trial of ALLO-715. Subject to regulatory acceptance, Servier may also use ALLO-647 in the Servier sponsored clinical trials of UCART19. However, we may be unable to agree with Servier an appropriate arrangement for the use of ALLO-647, and we are dependent on Servier's ability to progress the UCART19 trials. ALLO-647 may also cause adverse events, such as those events that alemtuzumab may cause. In addition, we may have to license certain rights relating to ALLO-647 from third parties. If we are unable to secure such rights, we may not be able to progress the commercialization of ALLO-647.

If we are unable to successfully develop and manufacture ALLO-647 in the timeframe we anticipate, or at all, or if the FDA does 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 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. The facility requires substantial improvements and there can be no assurance that we will complete the build-out of our manufacturing facility in a timely manner or at all. 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 dose will affect our ability to scale and our costs per dose. For instance, because ALLO-715 may require a higher dose than ALLO-501, it is possible that it may be more difficult to scale ALLO-715 production. As a result, we may never be able to develop a commercially viable product. The commercial manufacturing facility we develop 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 current good manufacturing practices (cGMPs), 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 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 or our CMO 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 overseas.

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

The CALM and PALL clinical trials are currently being conducted in the United States and multiple countries in Europe, and we plan to globally develop our future 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;
- 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 geo-political actions, including war and terrorism.

These and other risks associated with our international operations and our collaborations with Servier and Cellectis, each based in France, 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. 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 Chairman, our President and Chief Executive Officer, our Chief Technical Officer and our Chief Financial Officer. In addition, we are currently dependent on our TSA with Pfizer for personnel support. 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 6, 2019, we had 151 full-time employees. As our development and commercialization plans and strategies develop, and as we continue to transition into operating as a public company, 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.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants, including Pfizer through the TSA, which expires after a certain period of time, to provide certain services, including certain research and development as well as general and administrative support. We plan to transition from Pfizer services and facilities throughout 2019 and the transition may significantly disrupt our operations and be more expensive than we expect. 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. 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 and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We may form or seek 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 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 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 Exclusive License and Collaboration Agreement with Servier requires significant research and development commitments that may not result in the development and commercialization of product candidates, including UCART19 and ALLO-501. 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.

In April 2018, we entered into an Asset Contribution Agreement with Pfizer pursuant to which we acquired certain assets and assumed certain liabilities from Pfizer, including an Exclusive License and Collaboration Agreement with Servier and other intellectual property for the development and administration of CAR T cells for the treatment of cancer. We also agreed to offer employment to certain Pfizer employees on terms no less favorable than the terms such employees enjoyed while being employed by Pfizer. We also entered into a TSA with Pfizer pursuant to which Pfizer provides us with certain services, including the services of their personnel, with respect to the assets that we purchased from Pfizer. Under the TSA, Pfizer also provides us with certain facilities and facility management services, which terminate in 2019.

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 and licenses with Cellectis and Servier, 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 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.

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 clinical development of our product candidates, including the planned clinical trials for UCART19, ALLO-501 and ALLO-715. 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. Further, if approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

As of March 31, 2019, we had $680.7 million in cash and cash equivalents and available-for-sale 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. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

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, and statutory, regulatory, and policy changes. 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.

Our operations, and those of our CMO, CROs and other contractors and consultants, could be subject to 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 planned 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. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully, offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, the purchasing, leasing, ordering or arranging for the purchase, lease, or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that may be alleged to be intended to induce prescribing, purchases or recommendations, include any payments of more than fair market value, and may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, a person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act and the civil monetary penalties statute;
- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal government programs that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government, including federal healthcare programs;
- the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by any trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services' (HHS) Centers for Medicare & Medicaid Services (CMS) information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we may be subject to state, local and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, we may be subject to the following: state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales and medical representatives; and state and foreign laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, some of who receive stock options as compensation, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and/or significant penalties. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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. When it goes into effect on January 1, 2020, the CCPA will require 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. Legislators have stated that amendments will be proposed to the CCPA before it goes into effect, but it remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact (possibly significantly) 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 clinical trial insurance for our ALPHA trial, 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.

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 several years, including 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 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.

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

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 and taxes may be limited. As a result of our most recent private placements, our IPO and other transactions that have occurred in 2018, we may have experienced, an "ownership change." We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership. We anticipate incurring significant additional net losses for the foreseeable future, and our ability to utilize net operating loss carryforwards associated with any such losses to offset future taxable income may be limited to the extent we incur future ownership changes. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, we may be unable to use all or a material portion of our net operating loss carryforwards and other tax attributes, which could adversely affect our future cash flows.

Risks Related to Our Reliance on Third Parties

We rely and will continue to rely on third parties, including Servier, 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. In addition, we depend on our collaborator, Servier, to sponsor and lead the conduct of the CALM and PALL clinical trials.

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 may 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.*

Servier is responsible for UCART19 manufacturing and is working with a CMO in Europe to provide clinical supply for the CALM and PALL clinical trials. Servier has experienced UCART19 supply issues that limited its ability to recruit new patients. ALLO-501 has the same molecular design as UCART19, but is produced by a different CMO using a different manufacturing process. ALLO-501 and ALLO-715 will be manufactured in the United States, at least initially, by a CMO, and we will manage other aspects of the supply, including planning, CMO oversight, disposition and distribution logistics. There can be no assurance that we or Servier will not experience additional supply or manufacturing issues in the future.

While we have leased space to build a manufacturing facility, we must currently rely on outside vendors to manufacture supplies and process our product candidates. 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. For instance, our CMO has certain responsibilities for storage of raw materials, and the damage or loss of such 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.

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 that we currently obtain through Cellectis, 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. 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 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.

Unlike autologous CAR T companies, we are also reliant on receiving healthy donor material to manufacture our product candidates. Variation in donor material or delay in receiving donor material that meets our specifications, including specifications required by regulatory authorities, could adversely affect our ability to manufacture sufficient supply of our product candidates.

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;
- 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 of UCART19 may, depending on the data, also result in the delay, suspension or termination of one or more clinical trials of UCART19, 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 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. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes 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 this recommendation is likely to be applicable to our UCART19 product candidate; however, this recommendation is not definitive until UCART19 obtains regulatory approval for commercialization.

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 product candidates.*

If and when our ongoing and planned Phase 1 clinical trials for UCART19, ALLO-501 and ALLO-715 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 UCART19, ALLO-501 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.

For ALLO-501, we may have additional difficulties progressing the ALPHA trial as we plan to introduce our second-generation version of ALLO-501 prior to the start of the Phase 2 portion of the ALPHA trial, and the FDA may disagree with the plan or require a complete Phase 1 study of the second-generation ALLO-501 product candidate.

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.

ALLO-647 will also require regulatory review prior to its use in new clinical trials and the FDA may not accept the use of ALLO-647 in our clinical trials in a timely manner or at all. In addition, 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 T cell product candidates. Additionally, regulatory authorities may seek to understand the contribution of the lymphodepletion regimen, including the use of an anti-CD52 antibody, to any treatment effect.

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 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 may 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. 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.

Regenerative Medicine Advanced Therapy designation, even if granted for any of our product candidates, 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 may seek Regenerative Medicine Advanced Therapy (RMAT) designation for one or more of our 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 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.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical studies conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the current U.S. President's administration may impact our business and industry. Namely, the current U.S. President's administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

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 or export restrictions in order to retain control of the technologies. 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 influential and we may not be able to convince them to use 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.

Third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including, but not limited to, the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third-party payors may require co-payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third-party payers rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third-party payers, and reduce the willingness of physicians to use our product candidates.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development.

We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in Europe, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. Some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if 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. We are still unsure of the full impact that the Affordable Care Act will have on our business.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, the U.S. President has signed two Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, commonly known as the "individual mandate", as part of the Tax Cuts and Jobs Act of 2017 (Tax Act). On January 22, 2018, the U.S. President signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. The Bipartisan Budget Act of 2018 (BBA), among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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.

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drugs. At the federal level, the U.S. President's administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the current U.S. President's administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage Plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to federal Anti-Kickback Statute safe harbors which, among other things, may affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the current U.S. President's administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

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.

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. 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 UCART19 and ALLO-501, and we hold the commercial rights to these product candidates in the United States. Under the Servier Agreement, we also have an exclusive option to obtain the same rights to additional product candidates targeting one additional cancer antigen. 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 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. 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 UCART19, ALLO-501 or another CAR-based product candidate 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 UCART19 and our other 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, 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 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.*

Prior to our IPO in October 2018, there was no public market for our common stock. We cannot assure you that an active, liquid trading market for our shares will develop or persist. You may not be able to sell your shares quickly or at a recently reported market price if trading in our common stock is not active. The trading price of our common stock following our IPO 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 our manufacturers or suppliers;
- 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;
- 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.

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 future 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.

We are an emerging growth company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (Exchange Act), which requires, among other things, that we file with the Securities and Exchange Commission (SEC) annual, quarterly and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and the Nasdaq Global Select Market to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) was enacted, pursuant to which the SEC adopted rules and regulations related to corporate governance and executive compensation, such as "say on pay" and proxy access. Emerging growth companies are permitted to implement many of these requirements over a longer period and up to five years following the completion of its initial public offering. We intend to take advantage of this legislation for as long as we are permitted to do so. Once we become required to implement these requirements, we will incur additional compliance-related expenses. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to continue to increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss, and may require us to reduce costs in other areas of our business or increase the prices of our products or services. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we have incurred substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

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, 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.

Sales of our common stock by current stockholders may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, and make it more difficult for you to sell shares of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have registered on Form S-8 all shares of common stock that are issuable under our 2018 Plan. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to the 2018 Plan, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.*

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We may also sell our common stock as part of entering into strategic alliances, creating joint ventures or collaborations or entering into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock.

Pursuant to the 2018 Plan, our management is authorized to grant stock options and RSU awards to our employees, directors and consultants.

The aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2018 Plan is 15,409,983 shares. Additionally, the number of shares of our common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each year and continuing through and including January 1, 2028, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

We have broad discretion in the use of the net proceeds from our IPO and may not use them effectively.

Our management has broad discretion in the application of the net proceeds from our IPO, including for any of the purposes described in the section of our final prospectus, filed with the SEC on October 11, 2018, titled “Use of Proceeds”. Because of the number and variability of factors that will determine our use of the net proceeds from our IPO, their ultimate use may vary substantially from the use described in the final prospectus. Our management might not apply our net proceeds in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from our IPO in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from our IPO in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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 chairman 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.

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 will 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 do not initiate coverage of us, 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 $3.5 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $29.6 million. Thus, net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were approximately $343.0 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, 2019, we have not used any of the net proceeds from our IPO. We are investing these funds in some combination of short- and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. We expect to use the net proceeds from our IPO as described under "Use of Proceeds" in the Prospectus. We cannot predict with certainty all of the particular uses for the net proceeds from our IPO, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to access additional financing, the relative success and cost of our research, preclinical and clinical development programs and whether we are able to enter into future licensing arrangements. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from our IPO.

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).
10.1	Lease Agreement, dated February 19, 2019, by and between the Registrant and Silicon Valley Gateway Technology Center, LLC (incorporated by reference to Exhibit 10.18 to the Registrant's Annual report on Form 10-K (File No. 001-38693), filed with the SEC on March 8, 2019).
10.2*	License Agreement, dated March 8, 2019, between the Registrant and Cellectis S.A.
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.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

* Certain portions of this exhibit (indicated by "[***]") have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.

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 7, 2019

By: */s/ David Chang*

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

Date: May 7, 2019

By: */s/ Eric Schmidt*

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

CERTAIN CONFIDENTIAL PORTIONS HAVE BEEN REDACTED FROM THIS EXHIBIT BECAUSE THEY ARE BOTH (i) NOT MATERIAL AND (ii) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED. INFORMATION THAT HAS BEEN OMITTED HAS BEEN IDENTIFIED IN THIS DOCUMENT WITH A PLACEHOLDER IDENTIFIED BY THE MARK "[***]".

LICENSE AGREEMENT

This License Agreement (the "**Agreement**") is entered into as of March 8, 2019 (the "**Effective Date**"), by and among Allogene Therapeutics, Inc., a corporation organized and existing under the laws of the State of Delaware and having a place of business at 210 East Grand Avenue, South San Francisco, California, 94080 ("**Allogene**") and Cellectis SA, a corporation organized and existing under the laws of France and having a place of business at 8 rue de la Croix Jarry, 75013 Paris, France ("**Cellectis**"). Allogene and Cellectis may each be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Cellectis and Pfizer, Inc. ("**Pfizer**") entered into a Research Collaboration and License Agreement dated as of June 17, 2014, as amended on December 1, 2016 (the "**Research Collaboration and License Agreement**") pursuant to which Cellectis and Pfizer performed certain research services ("Research Plan Services") according to a defined program (the "Research Program") and a defined plan (the "Research Plan") in connection with a research collaboration during the period from June 18, 2014 to June 17, 2018 (the "Research Term"), and each of Cellectis and Pfizer granted to each other certain licenses and other rights to develop and commercialize specified CAR-T products.

WHEREAS, in connection with the sale by Pfizer to Allogene, of certain assets to which the Research Collaboration and License Agreement relates, Pfizer has assigned the Research Collaboration and License Agreement to Allogene effective as of April 6, 2018 (the "**Assignment**").

WHEREAS, as the Research Plan Services have been completed and the Research Term has expired (both under the Research Collaboration and License Agreement), Allogene and Cellectis have terminated the Research Collaboration and License Agreement.

WHEREAS, notwithstanding such termination, Allogene and Cellectis desire to execute this Agreement, to reflect the ongoing relationship between Cellectis and Allogene, pursuant to which each of Allogene and Cellectis will grant licenses and other rights to the other Party, including certain intellectual property rights that arose as a result of the Research Plan Services, in each case as further set forth herein.

NOW, THEREFORE, in consideration of the mutual promises and covenants set forth below and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows:

1. DEFINITIONS.

When used in this Agreement, the following capitalized terms will have the meanings set forth in this Article 1. Any terms defined elsewhere in this Agreement will be given equal weight and importance as though set forth in Article 1.

1.1. "**Additional Third Party Licenses**" is defined in Section 5.2.2(b).

1.2. "**Affiliate**" means, with respect to any Person, any other Person that controls, is controlled by or is under common control with such Person. A Person will be regarded as in control of another entity if it owns or controls at least fifty percent (50%) of the equity securities of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority), provided, however, that the term "Affiliate" will not include subsidiaries or other entities in which a Party or its Affiliates owns a majority of the ordinary voting power necessary to elect a majority of the board of directors or other managing authority, but is restricted from electing such majority by contract or otherwise, until such time as such restrictions are no longer in effect.

1.3. "**Agreement**" is defined in the introduction to this Agreement.

1.4. "**Agreement CAR-T**" means any CAR-T utilizing the Cellectis Technology that is identified, created or developed Targeting an Allogene Target.

1.5. **"Alliance Manager"** is defined in Section 2.3.

1.6. "**Allogene CAR-T Developed IP**" **[*****]

1.7. "**Allogene Diligence Obligation**" is defined in Section 2.2.3.

1.8. "**Allogene Improvements**" **[*****]

1.9. "**Allogene Indemnified Party**" is defined in Section 10.3.

1.10. "**Allogene Know-How**" means any Know-How comprised in the Allogene Technology.

1.11. "**Allogene Licensed Product**" means any product containing an Agreement CAR-T that is claimed or covered by, or was made using or otherwise incorporates, any Licensed Cellectis Intellectual Property.

1.12. "**Allogene Patent Right**" means any Patent Right comprised in the Allogene Technology.

1.13. "**Allogene Target**" means each of the Targets listed on Schedule 1.13 of this Agreement.

1.14. **"Allogene Technology**" [***]

1.15. "**Annual Net Sales**" means, with respect to any Allogene Licensed Product in a Calendar Year during the applicable Royalty Term for such Allogene Licensed Product, the aggregate Net Sales by Allogene, its Affiliates and its Sublicensees from the sale of such Allogene Licensed Product in the Territory during such Calendar Year.

1.16. "**Applicable Law**" means the laws, statutes, rules, regulations, guidelines, or other requirements that may be in effect from time to time and apply to a Party's activities to be performed under this Agreement, including any such laws, statutes, rules, regulations, guidelines, or other requirements of the FDA or the EMA.

1.17. "**Applicable Allogene Technology**" means any (a) Know-How Controlled by Allogene or its Affiliates that was invented, discovered or developed during the term of the Research Collaboration and License Agreement or the Term and in connection with Allogene's (or Pfizer's or its Affiliates', prior to the Assignment) or its Affiliates' activities under the Research Collaboration and License Agreement or this Agreement and (b) Patent Rights Controlled by Allogene or its Affiliates as of the date of termination of the Research Term, to the extent that such Patent Right claims any Know-How described in clause (a) above, to the extent that such Know-How and Patent Rights are necessary for the further development, manufacture and commercialization of Continuation Products.

1.18. "**Binding Obligation**" means, with respect to a Party (a) any oral or written agreement or arrangement that binds or affects such Party's operations or property, including any assignment, license agreement, loan agreement, guaranty, or financing agreement; (b) the provisions of such Party's charter, bylaws or other organizational documents or (c) any order, writ, injunction, decree or judgment of any court or Governmental Authority entered against such Party or by which any of such Party's operations or property are bound.

1.19. "**Biosimilar Biologic Product**" is defined in Section 5.2.2(a).

1.20. "**Biosimilar Notice**" means a copy of any application submitted by a Third Party to the FDA under 42 U.S.C. § 262(k) of the PHS Act (or, in the case of a country of the Territory outside the United States, any similar law) for Regulatory Approval of a biological product, which application identifies an Allogene Licensed Product as the reference product with respect to such product, and other information that describes the process or processes used to manufacture the biological product.

1.21. "**BLA**" means a Biologics License Application filed with the FDA in the United States with respect to a Licensed Product, as defined in Title 21 of the U.S. Code of Federal Regulations, Section 601.2 et. seq.

1.22. "**Business Day**" means a day other than a Saturday, a Sunday or a day that is a national holiday in the United States.

1.23. "**Calendar Quarter**" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31, for so long as this Agreement is in effect.

1.24. "**Calendar Year**" means each successive period of twelve (12) calendar months commencing on January 1 and ending on December 31.

1.25. "**CAR**" means a chimeric antigen receptor expressed from an experimentally validated Cellectis viral construct with specific molecular architecture and signaling domain sequences.

1.26. "**CAR-T**" means a population of T-cells with a unique set of experimentally validated biologic attributes expressing a CAR construct produced using Cellectis Technology.

1.27. **"Cellectis CAR-T Developed IP"** means Developed IP directed to the manufacture, composition or use of CAR-Ts Targeting a Cellectis Program Target.

1.28. "**Cellectis Improvement**" [***]

1.29. "**Cellectis Indemnified Party**" is defined in Section 10.2.

1.30. "**Cellectis Insolvency Event**" means the occurrence of any of the following: (a) a case is commenced by or against Cellectis under applicable bankruptcy, insolvency or similar laws, (b) Cellectis files for or is subject to the institution of bankruptcy, reorganization, liquidation, receivership or similar proceedings, (c) Cellectis assigns all or a substantial portion of its assets for the benefit of creditors, (d) a receiver or custodian is appointed for Cellectis' business, (e) a substantial portion of Cellectis' business is subject to attachment or similar process, (f) Cellectis suspends or threatens to suspend making payments with respect to all or any class of its debts or (g) anything analogous to any of the events described in the foregoing clauses (a) through (f) occurs under the laws of any applicable jurisdiction.

1.31. "**Cellectis Know-How**" means any Know-How comprised in the Cellectis Technology that was introduced into the Research Program by Cellectis pursuant to the applicable Research Plan under the Research Collaboration and License Agreement.

1.32. "**Cellectis Patent Right**" means any Patent Right comprised in the Cellectis Technology. The Cellectis Patent Rights existing as of June 17, 2014 include those set forth on Schedule 1.32 attached hereto.

1.33. "**Cellectis Product**" means any product incorporating a CAR-T Targeting a Cellectis Program Target which would infringe a Valid Claim of any Licensed Allogene Intellectual Property in the absence of the Licenses from Allogene pursuant to Section 4.2 or that is claimed or covered by, or was made using or otherwise incorporates, any Allogene Intellectual Property or Developed IP.

1.34. "**Cellectis Program Target**" means the Targets listed in Schedule 1.34.

1.35. "**Cellectis Technology**" [***]

1.36. "**Cellectis Third Party Agreement**" means any agreement between Cellectis and any Third Party under which Cellectis obtains rights in or to any Cellectis Licensed Intellectual Property.

1.37. "**Change of Control**" means, with respect to a Party, (a) a merger, reorganization or consolidation of such Party with a Third Party which results in the voting securities of such Party outstanding immediately prior thereto ceasing to represent at least fifty (50%) of the combined voting power of the surviving entity immediately after such merger, reorganization or consolidation, (b) a Third Party becoming the beneficial owner of fifty (50%) or more of the combined voting power of the outstanding securities of such Party or (c) the sale or other transfer to a Third Party of all or substantially all of such Party's business or assets to which this Agreement relates.

1.38. "**Combination Product**" means an Allogene Licensed Product containing an Agreement CAR-T and one or more other therapeutically active ingredients.

1.39. "**Commercialization**" or "**Commercialize**" means activities directed to marketing, promoting, distributing, importing, exporting, using for commercial purposes or selling or having sold an Allogene Licensed Product. Commercialization will not include any activities related to Manufacturing or Development.

1.40. "**Commercially Reasonable Efforts**" [***]

1.41. "**Confidential Information**" of a Party means all Know-How or other information, including proprietary information and materials (whether or not patentable) regarding such Party's technology, products, business or objectives, that is communicated in any way or form by the Disclosing Party to the Receiving Party, either prior to or after the Effective Date of this Agreement (including any information disclosed pursuant to the Research Collaboration and License Agreement), and whether or not such Know-How or other information is identified as confidential at the time of disclosure. The terms and conditions of this Agreement will be deemed to be the Confidential Information of each Party. Cellectis Improvements will be deemed to be the Confidential Information of Cellectis. Allogene Improvements will be deemed to be the Confidential Information of Allogene. Developed IP will be deemed to be the Confidential Information of each Party, except that Allogene CAR-T Developed IP is deemed to be the Confidential Information solely of Allogene, and Cellectis CAR-T Developed IP is deemed to be Confidential Information solely of Cellectis. For clarity, any Pfizer Confidential Information under the Research Collaboration and License Agreement shall be considered Allogene Confidential Information under this Agreement. Any Cellectis Confidential Information provided to Pfizer under the Research Collaboration and License Agreement shall be considered Cellectis Confidential Information under this Agreement.

1.42. "**Continuation Product**" is defined in Section 9.6.3(c).

1.43. "**Control**" or "**Controlled**" means, with respect to any (a) item of information, including Know-How, or (b) intellectual property right, the possession (whether by ownership interest or license, other than pursuant to this Agreement) by a Party of the ability to grant to the other Party access to or a license under such item or right, as provided herein, without violating the terms of any agreement or other arrangements with any Third Party.

1.44. "**Develop**" or "**Development**" means to discover, research or otherwise develop a product, including conducting any pre-clinical, non-clinical or clinical research and any drug development activity, including discovery, research, toxicology, pharmacology and other similar efforts, test method development and stability testing, manufacturing process development, formulation development, delivery system development, quality assurance and quality control development, statistical analysis, clinical studies (including pre- and post-approval studies), development of diagnostic assays in connection with clinical studies, and all activities directed to obtaining any Regulatory Approval, including any marketing, pricing or reimbursement approval.

1.45. "**Developed IP**" [***]

1.46. "**Development Milestone**" is defined in Section 5.1.1.

1.47. "**Development Milestone Payment**" is defined in Section 5.1.1.

1.48. "**Diligence Issue**" is defined in Section 2.2.4.

1.49. "**Disclosing Party**" is defined in Section 7.1.

1.50. "**Effective Date**" is defined in the introduction to this Agreement.

1.51. "**EMA**" means the European Medicines Agency, or any successor agency thereto.

1.52. "**Escalation Process**" is defined in Section 11.11.

1.53. "**FD&C Act**" means the United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.), as amended, and the rules and regulations promulgated thereunder.

1.54. "**FDA**" means the United States Food and Drug Administration or any successor agency thereto.

1.55. "**Field**" means human oncologic therapeutic, diagnostic, prophylactic and prognostic purposes.

1.56. "**First Commercial Sale**" means, with respect to any Allogene Licensed Product and any country of the world, the first sale of such Allogene Licensed Product under this Agreement by Allogene, its Affiliates or its Sublicensees to a Third Party in such country, after such Allogene Licensed Product has been granted Regulatory Approval by the competent Regulatory Authorities in such country.

1.57. "**GAAP**" means United States generally accepted accounting principles, consistently applied.

1.58. "**Generic Competition**" is defined in Section 5.2.2(a).

1.59. "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any national, state, county, city or other political subdivision.

1.60. "**ICC**" is defined in Section 11.12.

1.61. "**IND**" means an Investigational New Drug Application, as defined in the FD&C Act, that is required to be filed with the FDA before beginning clinical testing of an Allogene Licensed Product or Cellectis Product, as applicable, in human subjects, or an equivalent foreign filing.

1.62. "**Indemnified Party**" is defined in Section 10.4.1.

1.63. "**Indemnifying Party**" is defined in Section 10.4.1.

1.64. "**Joint Developed IP**" is defined in Section 6.1.1(c).

1.65. "**Joint Patent Right**" is defined in Section 6.2.1(d).

1.66. "**Know-How**" means any proprietary invention, discovery, data, information, process, method, technique, material, technology, result or other know-how, whether or not patentable.

1.67. "**Law**" means any law, statute, rule, regulation, order, judgment or ordinance of any Governmental Authority.

1.68. "**Liability**" is defined in Section 10.2.

1.69. "**License**" is defined in Section 4.1.1.

1.70. "**Licensed Cellectis Intellectual Property**" means any and all intellectual property (including Patent Rights and Know-How) Controlled by Cellectis, including the Cellectis Technology, the Cellectis Improvements and Cellectis' interest in the Developed IP, for Allogene to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit and Commercialize Allogene Licensed Products.

1.71. "**Licensed Allogene Intellectual Property**" means any and all Allogene Technology, Allogene Improvement, and Allogene's interest in the Developed IP, for Cellectis to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit and Commercialize Cellectis Products.

1.72. "**Litigation Conditions**" is defined in Section 10.4.2.

1.73. "**MAA**" means an application with the EMA seeking Regulatory Approval of a Licensed Product in Europe using the EMA's centralized procedure.

1.74. "**Major EU Market Country**" means any of [***].

1.75. "**Major Market Country**" means any Major EU Market Country, [***].

1.76. "**Manufacturing**" or "**Manufacture**" means activities directed to making, producing, manufacturing, processing, filling, finishing, packaging, labeling, quality assurance testing and release, shipping or storage of a product.

1.77. "**Marginal Royalty Rates**" is defined in Section 5.2.

1.78. [***]

1.79. "**Misuse**" means any use of Cellectis Confidential Information or Know-How by Allogene in violation of Allogene's non-use obligations pursuant to this Agreement or outside the scope of the licenses granted hereunder. For the avoidance of doubt, "Misuse" will not include Allogene's disclosure of Cellectis Confidential Information to any Third Party in violation of Article 7.

1.80. "**Misuse Allegation**" is defined in Section 11.11.

1.81. "**Most Advanced Targets**" is defined in Section 2.2.5.

1.82. "**Necessary**" is defined in Section 5.2.2(b).

1.83. "**Net Sales**" [***]

1.83.1. [***]

1.83.2. [***]

1.83.3. [***]

1.84. "**Non-Disclosing Party**" is defined in Section 7.3.2.

1.85. "**Notice of Dispute**" is defined in Section 11.10.1.

1.86. "**Other Cellectis Target**" means the Targets listed in Schedule 1.86.

1.87. **"Other Field"** means anti-tumor adoptive immunotherapy.

1.88. **"Other Products"** [***]

1.89. **"Other Territory"** means the United States of America together with any additional territories as amended from time to time by Cellectis at the written direction of Servier pursuant to the Servier Agreement.

1.90. "**Party**" and "**Parties**" is defined in the introduction to this Agreement.

1.91. "**Patent Rights**" means any and all (a) patents, (b) pending patent applications, including all provisional applications, substitutions, continuations, continuations-in-part, divisions and renewals, and all patents granted thereon, (c) all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including patent term extensions, supplementary protection certificates or the equivalent thereof, (d) inventor's certificates, (e) any other form of government-issued right substantially similar to any of the foregoing and (f) all United States and foreign counterparts of any of the foregoing. The Patent Rights owned by either Party include any Patent Right assigned to such Party pursuant to the provisions of this Agreement.

1.92. "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision or department or agency of a government.

1.93. "**Phase I Clinical Trial**" means a study of an Allogene Licensed Product in human subjects or patients with the endpoint of determining initial tolerance, safety, metabolism or pharmacokinetic information and clinical pharmacology of such product as and to the extent defined for the United States in 21 C.F.R. § 312.21(a), or its successor regulation, or the equivalent regulation in any other country. A so-called Phase I/II Clinical Trial will be deemed to be a Phase I Clinical Trial unless such study, when completed, allows Allogene to proceed directly to a Phase III Clinical Trial.

1.94. "**Phase II Clinical Trial**" means a study of an Allogene Licensed Product in human patients to determine the safe and effective dose range in a proposed therapeutic indication as and to the extent defined for the United Sates in 21 C.F.R. § 312.21(b), or its successor regulation, or the equivalent regulation in any other country.

1.95. "**Phase III Clinical Trial**" means a study of an Allogene Licensed Product in human patients with a defined dose or a set of defined doses of an Allogene Licensed Product designed to (a) ascertain efficacy and safety of such Allogene Licensed Product for its intended use; (b) define warnings, precautions and adverse reactions that are associated with the Allogene Licensed Product in the dosage range to be prescribed; and (c) support preparing and submitting applications for Regulatory Approval to the competent Regulatory Authorities in a country of the world, as and to the extent defined for the United States in 21 C.F.R.§ 312.21(c), or its successor regulation, or the equivalent regulation in any other country.

1.96. "**PHS Act**" means the United States Public Health Service Act, as amended, and the rules and regulations promulgated thereunder.

1.97. "**Price Approval**" means, in any country where a Governmental Authority authorizes reimbursement for, or approves or determines pricing for, pharmaceutical products, receipt (or, if required to make such authorization, approval or determination effective, publication) of such reimbursement authorization or pricing approval or determination (as the case may be)

1.98. "**Receiving Party**" is defined in Section 7.1.

1.99. "**Regulatory Approval**" means all technical, medical and scientific licenses, registrations, authorizations and approvals (including approvals of BLAs, MAAs, supplements and amendments, pre- and post- approvals, pricing and Third Party reimbursement approvals, and labeling approvals) of any Regulatory Authority, necessary for the use, Development, Manufacture and Commercialization of a pharmaceutical product in a regulatory jurisdiction. For the sake of clarity, Regulatory Approval will not be achieved for an Allogene Licensed Product in a country until all applicable Price Approvals have also been obtained by Allogene, its Affiliates, sublicensees or distributors, where applicable, for such Allogene Licensed Product in such country.

1.100. "**Regulatory Approval Application**" means any application submitted to an appropriate Regulatory Authority seeking any Regulatory Approval.

1.101. "**Regulatory Authority**" means, with respect to any national, supra-national, regional, state or local regulatory jurisdiction, any agency, department, bureau, commission, council or other governmental entity involved in the granting of a Regulatory Approval for such jurisdiction.

1.102. "**Representative**" is defined in Section 7.2.1.

1.103. "**Research Collaboration and License Agreement**" is defined in the introduction to this Agreement.

1.104. "**Research Plan"** is defined in the introduction of this Agreement.

1.105. **"Research Plan Services"** is defined in the introduction of this Agreement.

1.106. **"Research Program"** is defined in the introduction of this Agreement.

1.107. **"Research Term"** is defined in the introduction of this Agreement.

1.108. "**Royalty Term**" means, on an Allogene Licensed Product-by-Allogene Licensed Product and country-by-country basis, the period of time from the First Commercial Sale of such Allogene Licensed Product in such country until the later of (i) the expiration of the last Valid Claim that would, but for the license to or ownership by Allogene hereunder, be infringed by the sale of such Allogene Licensed Product in such country; (ii) the loss of regulatory exclusivity for the Allogene Licensed Product in such country or (iii) the tenth (10^{th}) anniversary of the date of the First Commercial Sale of such Allogene Licensed Product in such country, but in no event later than the twentieth (20^{th}) anniversary of the date of the First Commercial Sale in any country.

1.109. "**Rules**" is defined in Section 11.12.

1.110. "**Sales Milestone**" is defined in Section 5.1.2.

1.111. "**Sales Milestone Payment**" is defined in Section 5.1.2.

1.112. "**Sales Threshold**" is defined in Section 5.1.2.

1.113. "**SEC**" means the United States Securities and Exchange Commission.

1.114. **"Servier"** means Les Laboratoires Servier, a corporation organized and existing under the laws of France and having a place of business located at 50 rue Carnot, 92150 Suresnes, France.

1.115. "**Servier Agreement**" means that certain Research, Product Development, Option, License and Commercialization Agreement by and between Servier and Cellectis dated February 7, 2014, as amended and terminated; and the License, Development, Option, and Commercialization Agreement by and between Servier and Cellectis dated March 6, 2019.

1.116. "**Sublicensee**" means any Person to whom Allogene grants or has granted, directly or indirectly, a sublicense of rights licensed by Cellectis to Allogene under this Agreement, in accordance with the provisions of this Agreement.

1.117. "**[***] Patent Rights**" means the Patent Rights set forth on Schedule 9.23 under the headings: CELLECTIS Patent Portfolio on [***], In-licensed Patent applications from [***], In-Licensed patent applications from [***], In-Licensed Patent applications from [***] and In-Licensed Patent Rights from [***]. The value attributed to the [***] Patent Rights corresponds to [***] of the total value of the Cellectis Technology.

1.118. "**Target**" means (a) a specific biological molecule that is identified by a GenBank accession number or similar information, or by its amino acid or nucleic acid sequence, and (b) any biological molecule substantially similar in amino acid or nucleic acid sequence that has substantially the same biological function as a molecule disclosed in clause (a), including any naturally occurring mutant or allelic variant of a molecule disclosed in clause (a), including naturally occurring variants, mutants, transcriptional and post-transcriptional isoforms (e.g., alternative splice variants), and post-translational modification variants (e.g., protein processing, maturation and glycosylation variants); and (c) truncated forms (including fragments thereof) which have a biological function substantially similar to that of any biological molecules disclosed in clause (a) or clause (b).

1.119. "**Targeting**" means, when used to describe the relationship between a molecule and a Target, that the molecule (a) binds to the Target (or a portion thereof) and (b) is designed or being developed to exert its biological effect in whole or in part through binding to such Target (or such portion thereof).

1.120. "**Term**" is defined in Section 9.2.

1.121. "**Terminated Allogene Licensed Product**" is defined in Section 9.6.1(a).

1.122. "**Terminated Target**" is defined in Section 9.6.1.

1.123. "**Territory**" means the entire world.

1.124. "**Third Party**" means any Person other than Allogene, Cellectis or their respective Affiliates.

1.125. "**Third Party Claim**" is defined in Section 10.4.1.

1.126. "**Trademark**" means any trademark, trade dress, design, logo, slogan, house mark or name used in connection with the Commercialization of any Allogene Licensed Product by Allogene or its Affiliates or Sublicensees hereunder, including any registration or application for registration of any of the foregoing.

1.127. "**Useful**" is defined in Section 5.2.2(b).

1.128. "**Valid Claim**" means, with respect to a particular country, a claim of an issued and unexpired patent right included within the Licensed Intellectual Property or Developed IP that (i) has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental authority of competent jurisdiction, which decision is unappealed or unappealable within the time allowed for appeal, and (ii) has not been cancelled, withdrawn, abandoned, disclaimed or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise. An Allogene Licensed Product is "Covered" by a Valid Claim if its referenced activity by Allogene or its Sublicensees would, but for the licenses granted by Cellectis under this Agreement, infringe such Valid Claim.

1.129. **Construction**. Except where the context expressly requires otherwise, (a) the use of any gender herein will be deemed to encompass references to either or both genders, and the use of the singular will be deemed to include the plural (and vice versa), (b) the words "include", "includes" and "including" will be deemed to be followed by the phrase "without limitation," (c) the word "will" will be construed to have the same meaning and effect as the word "shall," (d) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), (e) any reference herein to any Person will be construed to include the Person's successors and assigns, (f) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (g) all references herein to sections or exhibits will be construed to refer to sections or exhibits of this Agreement, and references to this Agreement include all exhibits hereto, (h) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, (i) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent" or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise (but excluding e-mail and instant messaging), (j) references to any specific law, rule or regulation, or article, section or other division thereof, will be deemed to include the then-current amendments thereto or any replacement or successor law, rule or regulation thereof, (k) any definition of or reference to any agreement, instrument or other document herein will be construed as referring to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein), and (l) the term "or" will be interpreted in the inclusive sense commonly associated with the term "and/or."

2. EXCLUSIVITY AND DILIGENCE OBLIGATIONS.

2.1. **Exclusivity.** Subject to Sections 2.2.5, 4.1.2(e) and 4.5, during the Term of this Agreement, for each Allogene Target, neither Cellectis nor any of its Affiliates will (a) grant, or seek to grant, any right under any Cellectis Technology, Cellectis Improvements, Allogene Improvements licensed to Cellectis pursuant to Section 4.2.2 or Developed IP to any Third Party with respect to such Allogene Target or (b) use any Cellectis Technology, Cellectis Improvements, Allogene Improvements licensed to Cellectis pursuant to Section 4.2.2 or Developed IP to Develop (itself or through or with a Third Party) or Commercialize CAR-Ts Targeting such Allogene Target.

2.2. **Diligence.**

2.2.1. **Allogene Development Diligence**. Allogene will use Commercially Reasonable Efforts to Develop [***] for [***] during the Term. For avoidance of doubt, any actions taken by Allogene's Affiliates or Sublicensees under this Agreement will be treated as actions taken by Allogene in regard to satisfaction of the requirements of this Section 2.2.1.

2.2.2. **Commercial Diligence**. Allogene will use Commercially Reasonable Efforts to Commercialize [***] where Allogene has received Regulatory Approval for [***] in such country. Allogene will have no other diligence obligations with respect to the Commercialization of Allogene Licensed Products under this Agreement. For avoidance of doubt, any actions taken by Allogene's Affiliates or Sublicensees under this Agreement will be treated as actions taken by Allogene in regard to satisfaction of the requirements of this Section 2.2.2.

2.2.3. **Exceptions to Diligence Obligations**. Notwithstanding any provision of this Agreement to the contrary, Allogene will be relieved from and will have no obligation to undertake any efforts with respect to any diligence obligation under each of the Allogene Targets pursuant to Section 2.2.1 or Section 2.2.2 (each, an "**Allogene Diligence Obligation**") in the event that:

(a) Allogene receives or generates any safety, tolerability or other data reasonably indicating or signaling, as measured by Allogene's safety and efficacy evaluation criteria and methodology, that such Allogene Licensed Product has or would have an unacceptable risk-benefit profile or is otherwise not reasonably suitable for initiation or continuation of clinical trials in humans;

(b) Allogene receives any notice, information or correspondence from any applicable Regulatory Authority, or any applicable Regulatory Authority takes any action, that reasonably indicates that such Allogene Licensed Product is unlikely to receive Regulatory Approval; or

(c) the Allogene Diligence Obligation breach related to such Allogene Target is caused by the negligence, recklessness or intentional acts of Cellectis.

2.2.4. **Assertion of Diligence Obligation Claims**. If Cellectis is, becomes, or reasonably should be aware of facts that might form a reasonable basis that Allogene has failed to meet its Diligence Obligation then Cellectis will promptly notify Allogene in writing of such potential alleged performance failure (each such potential alleged performance failure, a "**Diligence Issue**"). Promptly upon Allogene's receipt of any notice of a Diligence Issue pursuant to this Section 2.2.4, the Allogene Alliance Manager and Cellectis Alliance Manager will meet to discuss the specific nature of such Diligence Issue and seek to identify an appropriate corrective course of action. If, no later than [***] after receipt of such a notice, (a) the Parties have not reached consensus regarding whether Allogene has failed to satisfy the Allogene Diligence Obligations and (b) the Parties' respective Alliance Managers have not agreed upon an appropriate corrective course of action for such Diligence Issue, then such Diligence Issue will be escalated and resolved pursuant to the dispute resolution provisions set forth in Section 11.10. If Cellectis fails to notify Allogene of a Diligence Issue pursuant to this Section 2.2.4 within [***] after the date that Cellectis first discovers or reasonably should have discovered such Diligence Issue, then Allogene will be deemed to have satisfied its Diligence Obligations, with respect to such Diligence Issue.

2.2.5. **Remedies for Breach of Allogene Diligence Obligations**. Subject to Section 2.2.3(c), if Allogene materially breaches any Allogene Diligence Obligation and fails to remedy such breach within ninety (90) days of Allogene's receipt of notice of such breach from Cellectis, then, with respect [***] Allogene Targets, [***] will cease to be an Allogene Target and will become a Cellectis Program Target and with respect to any Allogene Targets other than [***], the applicable Allogene Target(s) will no longer be subject to the exclusivity provisions set forth in Section 2.1 above.

2.3. **Alliance Manager.** Each of the Parties will appoint a single individual to serve as that Party's alliance manager ("Alliance Manager"). The role of each Alliance Manager will be to facilitate the relationship between the Parties as established by this Agreement.

3. PRODUCT DEVELOPMENT, MANUFACTURING, COMMERCIALIZATION AND REGULATORY MATTERS.

3.1. **General**. As of and from the Effective Date, Allogene will have sole authority over and control of the Development, Manufacture and Commercialization of Allogene Licensed Products Targeting such Allogene Target.

3.2. **Regulatory Approvals**. Allogene or its designated Affiliate(s) will file, in its own name, all Regulatory Approval applications for Allogene Licensed Products Targeting such Allogene Target where Allogene, in its sole discretion, determines it is commercially advantageous to do so. Allogene, or its designated Affiliate(s), will have the sole responsibility for, and sole authority with respect to, communications with any Regulatory Authority regarding any Regulatory Approval Application or any Regulatory Approval for an Allogene Licensed Product once granted. Except to the extent necessary to fulfill its obligations under Section 2.2.1, neither Allogene nor any of its Affiliates will have any obligation to seek Regulatory Approval for any Allogene Licensed Product.

3.3. **Control of Commercialization Activities**.

3.3.1. **General**. For each Allogene Target, Allogene will have sole and exclusive control over all matters relating to the Commercialization of Allogene Licensed Products Targeting such Allogene Target; and

3.3.2. **Trademarks**. Allogene will select and own all Trademarks used in connection with the Commercialization of any such Allogene Licensed Products, including all goodwill associated therewith. Neither Cellectis nor its Affiliates will use or seek to register, anywhere in the world, any trademarks which are confusingly similar to any Trademarks used by or on behalf of Allogene, its Affiliates or Sublicensees in connection with any Allogene Licensed Product. Nothing in this Section 3.3.2 will be construed to prevent Cellectis from granting Allogene any license or right in and to any trademark, trade dress, design, logo, slogan, house mark or name Controlled by Cellectis.

3.4. **Manufacturing**. Allogene will have the exclusive right (subject to Sections 2.2.4 and 4.5) to Manufacture Allogene Licensed Products Targeting such Allogene Target itself or through one or more Affiliates or Third Parties selected by Allogene. Allogene will have no diligence obligations with respect to the Manufacture of Allogene Licensed Products except to the extent necessary to fulfill the Allogene Diligence Obligations. Allogene will be responsible for 100% of the associated costs for the manufacturing of Allogene Licensed Products.

3.5. **Allogene Progress Reporting**. Commencing on the Effective Date and until delivery of the first royalty report pursuant to Section 5.4.2, Allogene will provide Cellectis with annual written reports on Allogene's activities to Develop and Commercialize Allogene Licensed Products Targeting such Allogene Target. Any information or written report provided by Allogene to Cellectis pursuant to this Section 3.5 will be deemed to be Allogene's Confidential Information subject to the provisions of Article 7.

3.6. **Right of First Refusal**.

In the event that Cellectis proposes to enter into any Third Party agreement related to the Development or Commercialization of any CAR Targeting a Cellectis Program Target (each a "**Cellectis Target Product**") in the Field, Cellectis will first provide Allogene with written notice of such proposal, including all material terms and conditions thereof (each a "**Cellectis Target Product Notice**"). For [***] following receipt of the Cellectis Target Product Notice, Allogene will have the option to purchase or license from Cellectis the Cellectis Target Product upon the terms and conditions set forth in the Cellectis Target Product Notice. In the event Allogene elects to purchase or license the Cellectis Target Product from Cellectis, Allogene will give written notice of its election to Cellectis within such [***] and the Parties will negotiate a mutually agreeable agreement for the purchase or license of the Cellectis Target Product within [***]; provided that the timeline for completing the agreement is not delayed by the actions or inactions of Cellectis. If Allogene does not elect to purchase or license the Cellectis Target Product, Cellectis may, within [***] following the expiration of the option right granted to Allogene, transfer or license the Cellectis Target Product to the proposed transferee or any other transferee, provided that this transfer will not be on terms and conditions more favorable to the transferee than those contained in the Cellectis Target Product Notice. In the event that Cellectis does not enter into the Third Party agreement to which the Cellectis Target Product Notice relates, this Section 3.6 will continue to apply with respect to the Cellectis Product Target. This Section 3.6 will be applicable to any potential Third Party agreement that Cellectis proposes entering into during the Term related to the Development or Commercialization of any CAR Targeting a Cellectis Program Target in the Field.

3.7. **Right of Negotiation**. In the event that Cellectis proposes to enter into any Third Party agreement related to the Development or Commercialization of any product Targeting an Other Cellectis Target, Cellectis will provide Allogene with written notice of such intent and will negotiate in good faith with Allogene regarding Allogene's purchase or license of such product Targeting an Other Cellectis Target.

4. LICENSES AND RELATED GRANTS OF RIGHTS.

4.1. **Grants to Allogene**.

4.1.1. **Exclusive License**. Subject to the terms and conditions of this Agreement, on an Allogene Target-by-Allogene Target basis, Cellectis hereby grants to Allogene and its Affiliates an exclusive (even as to Cellectis) license under the Licensed Cellectis Intellectual Property (excluding [***] Patent Rights), to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit and Commercialize Allogene Licensed Products in the Field in the Territory, with the right to sublicense as provided in Section 4.1.4 (the "**License**").

4.1.2. [***] **Patent Rights**.

(a) Subject to the terms and conditions of this Agreement on an Allogene Target-by-Allogene Target basis, Cellectis hereby grants to Allogene and its Affiliates the right to use the [***] engineered by Cellectis to Develop Allogene Licensed Products until the filing of an IND for each Allogene Licensed Product, in the Field.

(b) Subject to the terms and conditions of this Agreement on an Other Product-by-Other Product basis and effective as of October 30, 2015 (or such later date as such Other Product is included hereunder pursuant to the Servier Agreement), Cellectis hereby grants to Allogene and its Affiliates the right to use the [***] engineered by Cellectis pursuant to the Servier Agreement to Develop Other Products, and Cellectis shall further have the obligation to grant the rights set forth in this Section 4.l.2(b) to subcontractors as directed by Allogene pursuant to Section 4.l.5(b) herein, until the filing of an IND for each Other Product, in the Other Field.

(c) Subject to the terms and conditions of this Agreement, on an Allogene Target-by-Allogene Target basis and effective upon the filing of an IND for each individual Allogene Licensed Product developed under Section 4.1.2(a), Cellectis hereby grants to Allogene and its Affiliates an exclusive (even as to Cellectis) license under the [***] Patent Rights, to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit and Commercialize such Allogene Licensed Product in the Field in the Territory, with the right to sublicense as provided in Section 4.1.4. Notwithstanding the foregoing, Allogene hereby acknowledges and agrees that Cellectis shall have the right and obligation to grant licenses and rights to a Third Party as set forth in Section 4.1.5(b) and Allogene's license and other rights under the [***] Patent Rights shall be limited accordingly so long as any such agreement remains in effect with such Third Party. For the sake of clarity, the license granted to Allogene by Cellectis herein does not give Allogene the right [***].

(d) Subject to the terms and conditions of this Agreement, on an Other Product-by-Other Product basis and effective upon the filing of an IND for each individual Other Product developed under Section 4.1.2(b), Cellectis hereby grants to Allogene and its Affiliates an exclusive (even as to Cellectis) license under the [***] Patent Rights, to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit and Commercialize such Other Product in the Other Field in the Other Territory, and Cellectis shall further have the obligation to grant the licenses and rights set forth in this Section 4.1.2(d) to subcontractors as directed by Allogene pursuant to Section 4.1.5(b) herein. For the sake of clarity, the license granted to Allogene by Cellectis herein does not give Allogene the right [***].

(e) Pursuant to Section 4.1.2(e) of the Research Collaboration and License Agreement, Allogene consented to the license granted by Cellectis to Servier pursuant to the Servier Agreement. Further, the Parties acknowledged and agreed and hereby acknowledge and agree that any rights or licenses that have been granted to Servier at Allogene's request (including any expansions of such rights or licenses, pursuant to the Research Collaboration and License Agreement, that Allogene directs Cellectis in writing to grant to Servier), or that may hereafter be granted by Cellectis to Servier, a subcontractor as directed by Servier, or a Third Party at the request of Allogene, are rights or licenses that were provided to Allogene pursuant to the Research Collaboration and License Agreement or this Agreement, and therefore Cellectis has already received (or, in the future and in accordance with the terms of this Agreement, will have the right to receive) compensation that Cellectis and Allogene have determined is fair and equitable and that Cellectis shall therefore not have the right to any additional payments or compensation from Servier, Allogene or any other person or entity in connection with the foregoing. Without limiting the foregoing, the Parties also agreed and acknowledged that all consideration paid or to be paid, whether one-time payments, milestone payments, royalty payments or otherwise, to Cellectis under the Servier Agreement, the Research Collaboration and License Agreement, or this Agreement shall not be reduced or otherwise modified or amended because of the license granted to Servier or other parties as contemplated thereby.

4.1.3. **License to Cellectis Improvements**. Subject to the terms and conditions of this Agreement, Cellectis hereby grants to Allogene and its Affiliates a non-exclusive, worldwide, sublicensable, royalty-free, perpetual and irrevocable license under any Cellectis Improvements that were solely or jointly invented by the employees, agents or independent contractors of Allogene or its Affiliates to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit and Commercialize any products and processes.

4.1.4. **Right to Sublicense**. Allogene will have the right to grant sublicenses to its Affiliates and Third Parties of any and all licenses granted to Allogene under this Agreement by Cellectis, provided that (a) Allogene will be jointly and severally responsible with its Sublicensees to Cellectis for failure by its Sublicensees to comply with the terms and conditions of this Agreement; (b) each sublicense will include obligations on the Sublicensee that are consistent with the terms of this Agreement; and (c) Allogene will remain responsible for the payment to Cellectis of all Milestone Payments and royalties payable with respect to the activities and Net Sales of any Sublicensee.

4.1.5. **Direct License**

(a) **Direct license to Affiliates**. Allogene may at any time request and authorize Cellectis to grant licenses directly to Affiliates of Allogene by giving written notice designating to which Affiliate a direct license is to be granted. Upon receipt of any such notice, Cellectis will enter into and sign a separate direct license agreement with such designated Affiliate of Allogene. All such direct license agreements will be consistent with the terms and conditions of this Agreement, except for such modifications as may be required by the laws and regulations in the country in which the direct license will be exercised. The Parties further agree to make any amendments to this Agreement that are necessary to conform the combined terms of such direct license agreements and this Agreement to the terms of this Agreement as set forth on the Effective Date. In countries where the validity of such direct license agreements requires prior governmental approval or registration, such direct license agreements will not become binding between the parties thereto until such approval or registration is granted, which approval or registration will be obtained by Allogene. All costs of making such direct license agreement(s), including Cellectis' reasonable attorneys' fees, under this Section 4.1.5 will be borne by Allogene. Cellectis may provide a copy of any such license or similar agreements (and this Agreement) to any direct or indirect licensors to the extent required to comply with the terms of any license agreement to which Cellectis is a party from time to time.

(b) **Direct License to Third Parties.** Allogene may at any time request and authorize Cellectis to grant the rights and licenses set forth in Sections 4.1.2(a), 4.1.2(b), 4.1.2(c) and 4.1.2(d) of this Agreement directly to third parties by giving written notice designating to which Third Party such direct right or license is to be granted. Upon receipt of any such notice, Cellectis will enter into and sign a separate direct license or similar agreement with such designated Third Party, which, to the extent involving [***] Patent Rights licensed to Cellectis by Life Technologies Corporation, must include a license in respect of all of the [***] Patent Rights. All such direct license or similar agreements will be consistent with the terms and conditions of this Agreement, except for such modifications as may be required by the laws and regulations in the country in which the direct license or right will be exercised. Cellectis may provide a copy of any such license or similar agreements to any of its direct or indirect licensors to the extent required to comply with the terms of any license agreement to which Cellectis is a party from time to time. The parties further agree and acknowledge that no additional consideration would be due to Cellectis from Allogene or such Third Party in respect of the grant of any such license or similar right, and the grant of any such license or similar right shall limit Allogene's license and other rights accordingly so long as any such agreement remains in effect with such Third Party. The parties acknowledge and agree that any rights or licenses that may hereafter be granted by Cellectis at the request of Allogene as contemplated by the immediately preceding sentence are rights or licenses that were previously provided to Allogene pursuant to this Agreement in accordance with the broad collaboration and development activities contemplated by such agreement, and therefore Cellectis has already received (or, in the future and in accordance with the terms of this Agreement, will have the right to receive) compensation that Cellectis and Allogene have determined is fair and equitable and that Cellectis shall therefore not have the right to any additional payments or compensation from Allogene or any other person or entity in connection with the foregoing. The parties further agree to make any amendments to this Agreement that are necessary to conform the combined terms of such direct license or similar agreements and this Agreement to the terms of this Agreement. In countries where the validity of such direct license or similar agreements requires prior governmental approval or registration, such direct license or similar agreements will not become binding between the parties thereto until such approval or registration is granted, which approval or registration will be obtained by Allogene or the Third Party, as applicable.

4.1.6. **Right of Reference**. Cellectis hereby grants to Allogene a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b), to any data Controlled by Cellectis or its Affiliates (a) that relates to the Licensed Cellectis Intellectual Property, the Agreement CAR-Ts, the Allogene Licensed Products or preclinical studies with respect to the Allogene Licensed Products and (b) that Allogene reasonably believes may be necessary or useful to the Development, Manufacturing or Commercialization of any Agreement CAR-T or any Allogene Licensed Product pursuant to this Agreement, and Cellectis will provide a signed statement to the foregoing effect, if so requested by Allogene in accordance with 21 C.F.R. § 314.50(g)(3).

4.1.7. **Technology Transfer Assistance to Allogene**. Cellectis will provide reasonable assistance, at no additional cost to Allogene, to affect the timely and orderly transfer to Allogene of the Know-How included in the Licensed Cellectis Intellectual Property necessary for the Development, Manufacturing and Commercialization of Allogene Licensed Products pursuant to the License.

4.2. **Grants to Cellectis**.

4.2.1. **Non-Exclusive License**. Subject to the terms and conditions of this Agreement, Allogene hereby grants to Cellectis and its Affiliates a non-exclusive, worldwide, royalty-free, perpetual and irrevocable license under the Licensed Allogene Intellectual Property Controlled by Allogene solely to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit and Commercialize Cellectis Products Targeting Cellectis Program Targets. Cellectis will have the right to grant sublicenses of the foregoing license to Third Party collaborators only if Cellectis has entered into a written agreement with such Third Party collaborator (a) obtaining a covenant not to sue or (b) granting Allogene a non-exclusive, worldwide, royalty-free, perpetual and irrevocable license under improvements to the Cellectis Technology developed in the framework of the collaboration between Cellectis and such Third Party that are Controlled by such Third Party.

4.2.2. **License to Allogene Improvements**. Subject to the terms and conditions of this Agreement, Allogene hereby grants to Cellectis and its Affiliates a non-exclusive, worldwide, sublicensable, royalty-free, perpetual and irrevocable license under any Allogene Improvements that were solely or jointly invented by the employees, agents or independent contractors of Cellectis or its Affiliates to make, have made, use, have used, sell, have sold, offer for sale, have offered for sale, import, have imported and otherwise exploit and Commercialize any products and processes.

4.2.3. **Technology Transfer Assistance to Cellectis**. Allogene will provide reasonable assistance, at no additional cost to Cellectis, to affect the timely and orderly transfer to Cellectis of the Know-How included in the Allogene Technology, Allogene Improvements, Developed IP solely owned by Allogene, and CAR-T Developed IP (if applicable) necessary for the Development, Manufacturing and Commercialization of Cellectis Products Targeting Cellectis Programs Targets pursuant to the License under Sections 4.2.1 and 4.2.2 above.

4.3. **Reciprocal Non-Exclusive Research License for Disclosed Know-How and Confidential Information**. Without limiting any other license granted to either Party under this Agreement and subject to the terms of Article7:

4.3.1. Cellectis hereby grants to Allogene and its Affiliates a non-exclusive, irrevocable, perpetual, non-transferable, royalty-free, fully paid-up, worldwide license to use any and all Cellectis Know-How included in the Licensed Cellectis Intellectual Property and Cellectis Confidential Information disclosed to Allogene (or Pfizer prior to the Assignment) during the term of the Research Collaboration and License Agreement or during the Term of this Agreement solely for internal research purposes.

4.3.2. Allogene hereby grants to Cellectis and its Affiliates a non-exclusive, irrevocable, perpetual, non-transferable, royalty-free, fully paid-up, worldwide license to use any and all Allogene Know-How and Allogene Confidential Information (other than any information regarding the identity of or Allogene's reasons for selecting any Allogene Target or Additional Allogene Target, which will only be disclosed by Cellectis to its Representatives as necessary to comply with the terms of this Agreement) disclosed to Cellectis during the term of the Research Collaboration and License Agreement or during the Term of this Agreement solely for internal research purposes.

4.3.3. Notwithstanding the foregoing, neither Allogene nor Cellectis will have any right under this Section 4.3 to make or use any physical material supplied by the other Party for use in the Research Program other than for use in the Research Program.

4.4. **Retained Rights**. For the avoidance of doubt, except as expressly provided in regard to the licenses contained in this Article 4 or in the provisions of Section 6.1.1, each Party will retain ownership of all of its Allogene Technology or Cellectis Technology, as applicable.

4.5. **Other Allogene Programs**. Cellectis understands and acknowledges that Allogene may have present or future initiatives or opportunities, including initiatives or opportunities with its Affiliates or Third Parties, involving similar products, programs, technologies or processes that are similar to or that may compete with a product, program, technology or process covered by this Agreement. Cellectis acknowledges and agrees that nothing in this Agreement will be construed as a representation, warranty, covenant or inference that Allogene will not itself Develop, Manufacture or Commercialize or enter into business relationships with one or more of its Affiliates or Third Parties to Develop, Manufacture or Commercialize products, programs, technologies or processes that are similar to or that may compete with any product, program, technology or process covered by this Agreement. Notwithstanding the foregoing, if Allogene or its Affiliates, other than pursuant to this Agreement, themselves Develop, Manufacture or Commercialize or enter into business relationships with one or more of its Affiliates or Third Parties to Develop, Manufacture or Commercialize T-cells expressing a chimeric antigen receptor construct other than a CAR-T, with respect to a particular Allogene Target in the Field, then any exclusive licenses granted to Allogene under this Agreement with respect to an Allogene Licensed Product Targeting such Allogene Target will be automatically converted into non-exclusive licenses, and Cellectis' exclusivity obligation under Section 2.1 will not apply with respect to such Allogene Target.

4.6. **No Implied Rights**. Except as expressly provided in this Agreement, neither Party will be deemed, by estoppel, implication or otherwise, to have granted the other Party any license or other right with respect to any intellectual property of such Party.

5. PAYMENTS TO CELLECTIS.

5.1. **Milestones**

5.1.1. **Development Milestones**. Within [***] of receipt of Cellectis' invoice following the first occurrence of each event described below (each, a "**Development Milestone**") for each Allogene Licensed Product for each Allogene Target, Allogene will pay to Cellectis the amount set forth below (each, a "**Development Milestone Payment**") to be payable only once with respect to each Allogene Licensed Product Targeting an Allogene Target. For the avoidance of doubt, if any Development Milestone Payment is paid for an Agreement CAR-T or Allogene Licensed Product Targeting an Allogene Target and the Development or Commercialization of such Agreement CAR-T or Allogene Licensed Product is terminated and such Agreement CAR-T or Allogene Licensed Product is replaced with another Agreement CAR-T or Allogene Licensed Product Targeting the same Allogene Target, such Development Milestone Payment will not be owed by Allogene if such Agreement CAR-T or Allogene Licensed Product later achieves the same Development Milestone.

Development Milestone	Development Milestone Payments
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

If any Development Milestone occurs before a previous Development Milestone occurs, then any Development Milestone that has not yet been paid for achievement of any previous Development Milestone shall become due upon the achievement of the subsequent Development Milestone and payable together with the payment due upon achievement of such subsequent Development Milestone. For clarity, the achievement of a Development Milestone related to [***] will not result in the payment of any other Development Milestone related to [***].

5.1.2. **Sales Milestones**. Allogene will pay to Cellectis the following one-time payments (each, a "**Sales Milestone Payment**") within [***] of the last day of the Calendar Year when aggregate Annual Net Sales of an Allogene Licensed Product in a Calendar Year first reach the respective threshold (a "**Sales Threshold**") indicated below (each, a "**Sales Milestone**"); provided that such Sales Threshold with respect to an Allogene Licensed Product must be reached within [***] following the First Commercial Sale of such Allogene Licensed Product in the Territory.

Total Annual Net Sales	Sales Milestone Payments
[***]	[***]
[***]	[***]

5.2. **Royalties**. With respect to each Allogene Licensed Product and subject to the provisions of Section 5.2.2, Allogene will pay Cellectis royalties in the amount of the applicable rates ("**Marginal Royalty Rates**") set forth below of Annual Net Sales of any Allogene Licensed Product Targeting such Allogene Target during the Royalty Term:

Annual Net Sales	Marginal Royalty Rates (% of the Annual Net Sales)
[***]	[***]
[***]	[***]

5.2.1. **Marginal Royalty Rate Application**. Each Marginal Royalty Rate set forth in the table above will apply only to that portion of the Annual Net Sales of a given Allogene Licensed Product in the Territory during a given Calendar Year that falls within the indicated range.

5.2.2. **Royalty Adjustments**. The following adjustments will be made, on an Allogene Licensed Product-by-Allogene Licensed Product and country-by-country basis, to the royalties payable pursuant to this Section 5.2:

(a) **Generic Competition**. Royalties payable following establishment of Generic Competition with respect to the sale by a Third Party of a product that is a Biosimilar Biologic Product to such Allogene Licensed Product in such country will be payable at [***] of the otherwise applicable rate prior to application of this Section 5.2.2(a). "**Generic Competition**" means, with respect to a given Calendar Year with respect to an Allogene Licensed Product in any country, that during such Calendar Year, one (1) or more Third Parties have received Regulatory Approval to sell in such country a Biosimilar Biologic Product, such Biosimilar Biologic Product(s) will be commercially available in such country and such Biosimilar Biologic Product(s) will have, in the aggregate. A product will be a "**Biosimilar Biologic Product**" with respect to an Allogene Licensed Product if such product (1) has been licensed as a biosimilar or interchangeable product by FDA pursuant to Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)), as may be amended, or any subsequent or superseding law, statute or regulation, (2) has been licensed as a similar biological medicinal product by EMA pursuant to Directive 2001/83/EC, as may be amended, or any subsequent or superseding law, statute or regulation, or (3) has otherwise achieved analogous Regulatory Approval from another applicable Regulatory Authority.

(b) **Third Party Patents**. If, after June 17, 2014, it was or is Necessary or Useful for Allogene (or Pfizer, to the extent identified by Pfizer prior to the Assignment) to license one or more Patent Rights from one or more Third Parties in order to Develop, Manufacture, Commercialize or use any Allogene Licensed Product, whether directly or through any Allogene Affiliate or Sublicensee, then Allogene may, in its sole discretion, negotiate and obtain a license under such Patent Right(s) (each such Third Party license, or any such Third Party license entered into as of the Effective Date by Allogene or by Pfizer and assigned to Allogene, referred to herein as an "**Additional Third Party License**"). Any royalty otherwise payable to Cellectis under this Agreement with respect to Net Sales of any Allogene Licensed Product by Allogene, its Affiliates or Sublicensees will be reduced by [***] of the amounts payable to Third Parties pursuant to any Additional Third Party Licenses, such reduction to continue until all such amounts have been expended, provided that in no event will the total royalty payable to Cellectis for any Allogene Licensed Product be less than [***] of the royalty amounts otherwise payable for such Allogene Licensed Product and in no event will the royalty payable to Cellectis for any Allogene Licensed Product be reduced below [***] (in each case, other than in the case of Cellectis' breach of any representation, warranty or covenant hereunder). For purposes of this Section 5.2.2(b), (i) "**Necessary**" means that, without a license to use the Third Party's Patent Right, the Development, Manufacture, Commercialization or use of any Allogene Licensed Product in the form such Allogene Licensed Product exists at the time that the Additional Third Party License is executed would, in Allogene's opinion, infringe such Third Party's Patent Right and (ii) "**Useful**" means that Allogene has determined in its discretion that use of such Third Party's Patent Right would enhance the commercial potential of such Allogene Licensed Product. For the avoidance of doubt, the Parties agree and acknowledge that this Section 5.2.2(b) will not apply with respect to royalties payable by Allogene to any Third Party under any agreement in existence as of June 17, 2014. Neither Party will intentionally negotiate with a Third Party an exclusive license that excludes sublicense rights to the other Party, in the event such Third Party rights are necessary, as determined by the negotiating Party, to Develop and Commercialize Allogene Licensed Products and Cellectis Products in connection with this Agreement in the Field.

(c) **Cellectis Third Party Agreements**. Cellectis will be solely responsible for all obligations, including royalty obligations, that are due and owing or may become due and owing with respect to any Cellectis Third Party Agreements that are in effect as of the Effective Date or that Cellectis or any of its Affiliates enters into during the Term of this Agreement.

5.2.3. **Fully Paid-Up, Royalty Free License**. After expiration of the Royalty Term for any Allogene Licensed Product in a country in the Territory, no further royalties will be payable in respect of sales of such Allogene Licensed Product in such country and thereafter the License with respect to such Allogene Licensed Product in such country will be a fully paid-up, perpetual, exclusive, irrevocable, royalty-free license.

5.3. **Diagnostic and Prognostic Products**. In no event will any milestone, net sales or royalty payments become due or owing pursuant to Section 5.1 or 5.2 above with respect to any Allogene Licensed Product Developed or Commercialized for diagnostic or prognostic purposes.

5.4. **Reports and Payments**.

5.4.1. **Cumulative Royalties**. The obligation to pay royalties under Section 5.2 will be imposed only once with respect to a single unit of an Allogene Licensed Product regardless of how many Valid Claims in Patent Rights included within the Licensed Cellectis Intellectual Property would, but for this Agreement, be infringed by the use or sale of such Allogene Licensed Product in the country in which such Allogene Licensed Product is used or sold.

5.4.2. **Royalty Statements and Payments**. Within [***] after the end of each Calendar Quarter, Allogene will deliver to Cellectis a report setting forth for such Calendar Quarter the following information, on an Allogene Licensed Product-by-Allogene Licensed Product basis: (a) the Net Sales of each Allogene Licensed Product, (b) the basis for any adjustments to the royalty payable for the sale of each Allogene Licensed Product and (c) the royalty due hereunder for the sale of each Allogene Licensed Product. No such reports will be due for any Allogene Licensed Product before the First Commercial Sale of such Allogene Licensed Product in the Territory. The total royalty due for the sale of Allogene Licensed Products during such Calendar Quarter will be remitted at the time such report is delivered to Cellectis.

5.4.3. **Taxes and Withholding**. It is understood and agreed between the Parties that any payments made under this Agreement are exclusive of any value added or similar tax ("**VAT**"), which will be added thereon as applicable. Where VAT is properly added to a payment made under this Agreement, the party making the payment will pay the amount of VAT only on receipt of a valid tax invoice issued in accordance with the laws and regulations of the country in which the VAT is chargeable. In addition, in the event any of the payments made by Allogene pursuant to this Agreement become subject to withholding taxes under the Laws of any jurisdiction, Allogene will deduct and withhold the amount of such taxes for the account of Cellectis, to the extent required by Law, such amounts payable to Cellectis will be reduced by the amount of taxes deducted and withheld, and Allogene will pay the amounts of such taxes to the proper Governmental Authority in a timely manner and promptly transmit to Cellectis an official tax certificate or other evidence of such tax obligations together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable Cellectis to claim such payment of taxes. Any such withholding taxes required under applicable Law to be paid or withheld will be an expense of, and borne solely by, Cellectis. Allogene will provide Cellectis with reasonable assistance to enable Cellectis to recover such taxes as permitted by Law.

5.4.4. **Currency**. All amounts payable and calculations hereunder will be in United States dollars. As applicable, Net Sales and any royalty deductions will be converted into United States dollars in accordance with Allogene's customary and usual conversion procedures, consistently applied.

5.4.5. **Method of Payment**. Except as permitted pursuant to Section 5.4.4, each payment hereunder will be made by electronic transfer in immediately available funds via either a bank wire transfer, an ACH (automated clearing house) mechanism, or any other means of electronic funds transfer, at Allogene's election, to such bank account as the Cellectis will designate in writing to Allogene at least forty-five (45) days before the payment is due.

5.4.6. **Additional Provisions Relating to Payments**. Cellectis acknowledges and agrees that nothing in this Agreement (including any schedules and exhibits hereto) will be construed as representing an estimate or projection of either (a) the number of Allogene Licensed Products that will or may be successfully Developed or Commercialized or (b) anticipated sales or the actual value of any Allogene Licensed Product. ALLOGENE MAKES NO REPRESENTATION OR WARRANTY, EITHER EXPRESS OR IMPLIED, THAT IT WILL BE ABLE TO SUCCESSFULLY DEVELOP OR COMMERCIALIZE ANY PRODUCT OR, IF COMMERCIALIZED, THAT IT WILL ACHIEVE ANY PARTICULAR SALES LEVEL OF SUCH PRODUCT(S), PROVIDED THAT THE FOREGOING WILL NOT LIMIT ALLOGENE'S OBLIGATIONS UNDER THIS AGREEMENT.

5.5. **Maintenance of Records; Audits**.

5.5.1. **Record Keeping**. Allogene will keep, and cause its Affiliates and Sublicensees to keep, accurate books of account and records in connection with the sale of Allogene Licensed Products, in sufficient detail to permit accurate determination of all figures necessary for verification of royalties to be paid hereunder. Allogene will maintain, and cause its Affiliates and Sublicensees to maintain, such records for a period of at least [***] after the end of the Calendar Year in which they were generated.

5.5.2. **Audits**. Upon thirty (30) days prior written notice from Cellectis, Allogene will permit an independent certified public accounting firm of internationally recognized standing selected by Cellectis and reasonably acceptable to Allogene to examine, at Cellectis' sole expense, the relevant books and records of Allogene during the period covered by such examination, as may be reasonably necessary to verify the accuracy of the reports submitted by Allogene in accordance with Section 5.4 and the payment of royalties hereunder. An examination by Cellectis under this Section 5.5.2 will occur not more than [***] and will be limited to the pertinent books and records for any Calendar Year ending not more than [***] before the date of the request. The accounting firm will be provided access to such books and records at Allogene's or its Affiliates' facilities where such books and records are kept and such examination will be conducted during Allogene's normal business hours. Allogene may require the accounting firm to sign a reasonable and customary non-disclosure agreement before providing the accounting firm access to Allogene's facilities or records. Upon completion of the audit, the accounting firm will provide both Allogene and Cellectis a written report disclosing whether the reports submitted by Allogene are correct or incorrect, whether the royalties paid are correct or incorrect and, in each case, the specific details concerning any discrepancies. No other information will be provided to Cellectis.

5.5.3. **Underpayments/Overpayments**. If such accounting firm concludes that additional royalties were due to Cellectis, Allogene will pay to Cellectis the additional royalties within thirty (30) days of the date Allogene receives such accountant's written report so concluding. If such underpayment exceeds [***] of the royalties that were to be paid to Cellectis, Allogene also will reimburse Cellectis for all reasonable charges of such accountants for conducting the audit. If such accounting firm concludes that Allogene overpaid royalties to Cellectis, Cellectis will repay such amount to Allogene in full within thirty (30) days of the receipt of such accountant's report, or, at Allogene's option, Allogene will be entitled to offset all such overpayments against any outstanding or future amounts payable to Cellectis hereunder until Allogene has received full credit for such overpayments.

5.5.4. **Confidentiality**. All financial information of Allogene which is subject to review under this Section 5.5 will be deemed to be Allogene's Confidential Information subject to the provisions of Article 7 hereof, and Cellectis will not disclose such Confidential Information to any Third Party or use such Confidential Information for any purpose other than verifying payments to be made by Allogene to Cellectis hereunder.

5.5.5. **Costs**. Cellectis shall pay the full cost of the audit unless the discrepancy is to the Cellectis' detriment and is greater than [***] of all amounts due in such calendar year, in which cases Allogene shall pay the reasonable cost charged by such accountant for such inspection.

5.6. **No Guarantee of Success**. Allogene and Cellectis acknowledge and agree that payments to Cellectis pursuant to Sections 5.1 and 5.2: (a) have been included in this Agreement on the basis that they are only payable or otherwise relevant if an Allogene Licensed Product is successfully Developed or Commercialized, as applicable; (b) are solely intended to allocate amounts that may be achieved upon successful Development or Commercialization of an Allogene Licensed Product between Allogene (who will receive all Allogene Licensed Product sales revenues) and Cellectis; (c) are not intended to be used and will not be used as a measure of damages if this Agreement is terminated for any reason, including pursuant to Allogene's right to terminate at for convenience, before any such success is achieved and such amounts become due; and (d) will only be triggered, and will only be relevant as provided, in accordance with the terms and conditions of such provisions. Allogene and Cellectis further acknowledge and agree that nothing in this Agreement will be construed as representing any estimate or projection of (i) the successful Development or Commercialization of any Allogene Licensed Product under this Agreement, (ii) the number of Allogene Licensed Products that will or may be successfully Developed or Commercialized under this Agreement, (iii) anticipated sales or the actual value of any Allogene Licensed Products that may be successfully Developed or Commercialized under this Agreement or (iv) the damages, if any, that may be payable if this Agreement is terminated for any reason. Allogene makes no representation, warranty or covenant, either express or implied, that (A) it will successfully Develop, Manufacture, Commercialize or continue to Develop, Manufacture or Commercialize any Allogene Licensed Product in any country, (B) if Commercialized, that any Allogene Licensed Product will achieve any particular sales level, whether in any individual country or cumulatively throughout the Territory or (C) Allogene will devote, or cause to be devoted, any level of diligence or resources to Developing or Commercializing any Allogene Licensed Product in any country, or in the Territory in general, other than is expressly required under Section 2.2.

6. INTELLECTUAL PROPERTY.

6.1. **Inventions**.

6.1.1. **Ownership**. All determinations of inventorship under this Agreement will be made in accordance with the laws of the United States.

(a) **Allogene Improvements**. Allogene will own all [***].

(b) **Cellectis Improvements**. Cellectis will own all [***].

(c) **Developed IP**. [***].

(d) **Allogene CAR-T Developed IP.** [***].

(e) **Cellectis CAR-T Developed IP.** [***].

(f) **Implementation**. Each Party will assign, and does hereby assign, to the other Party such Patent Rights, Know-How or other intellectual property rights as necessary to achieve ownership as provided in this Section 6.1.1. Each assigning Party will execute and deliver all documents and instruments reasonably requested by the other Party to evidence or record such assignment or to file for, perfect or enforce the assigned rights. Each assigning Party will make its relevant employees, agents and independent contractors (and their assignments and signatures on such documents and instruments) reasonably available to the other Party for assistance in accordance with this Section 6.1.1 at no charge.

6.1.2. **Disclosure**. Each Party will promptly (and in no event less than [***] before filing any initial Patent Right disclosing such intellectual property) disclose to the other Party any Developed IP, Cellectis Improvement or Allogene Improvement, including all invention disclosures or other similar documents submitted to such Party by its, or its Affiliates', employees, agents or independent contractors describing such Developed IP, Cellectis Improvement or Allogene Improvement, and the proposed inventorship of any new Patent Rights intended to be filed. The other Party will promptly raise any issue regarding inventorship. Any inventorship issue raised more than [***] after notice of the filing of an initial Patent Rights and the content thereof, or the subsequent filing of new patent claims in a Patent Right directed to substantially different inventions, will not affect ownership of the Patent Right as determined in accordance with the initial inventorship determination.

6.2. **Patent Rights**.

6.2.1. **Filing, Prosecution and Maintenance of Patent Rights**.

(a) **Cooperation**. Without limiting any other rights and obligations of the Parties under this Agreement, the Parties will cooperate with respect to the timing, scope and filing of patent applications and patent claims relating to any Cellectis Improvements, Allogene Improvements and Developed IP to preserve and enhance the patent protection for Agreement CAR-Ts, including the manufacture and use thereof. If the ownership rights in any Patent Rights included in Cellectis Improvements or Developed IP are substantially impeding or would substantially impede Allogene's prosecution of Allogene CAR-T Developed IP, or Cellectis's prosecution of Cellectis CAR-T Developed IP, the Parties will negotiate in good faith an amendment of the ownership of such Patent Rights included in Cellectis Improvements or Developed IP while preserving for each Party substantially the same rights, including all Milestone Payments and royalty payments, as are afforded in this Agreement.

(b) **Allogene Patent Rights**. Allogene, at its own expense, will have the sole right, but not the obligation, to prepare, file, prosecute and maintain, throughout the world, any Patent Rights that it solely owns, including Allogene Patent Rights and Patent Rights comprised in the Allogene Improvements and Allogene CAR-T Developed IP. Allogene will keep Cellectis informed regarding the status of any Patent Right comprised in any such CAR-T Developed IP at Cellectis' reasonable request. To the extent Allogene wishes not to file, prosecute or maintain any such Patent Right, Allogene will provide Cellectis with thirty (30) days prior written notice to such effect, in which event Cellectis may elect to continue filing, prosecution or maintenance of such Patent Right, and Allogene, upon Cellectis' written request received within such thirty (30) day period, will execute such documents and perform such acts, at Cellectis' expense, as may be reasonably necessary to permit Cellectis to file, prosecute and maintain such Patent Right. Any such Patent Right that is prosecuted or maintained by Cellectis pursuant to this Section 6.2.1(b): (i) will continue to be owned by Allogene, and (ii) subject to the Parties' other rights and obligations under this Agreement, may be licensed by Allogene to one or more Third Parties.

(c) **Cellectis Patent Rights**. Cellectis, at its own expense, will have the sole right, but not the obligation, to prepare, file, prosecute and maintain, throughout the world, any Patent Rights included in Licensed Intellectual Property that it solely owns or has in-licensed from Third Parties, including Cellectis Patent Rights and Patent Rights comprised in the Cellectis Improvements. Cellectis will not disclose any Allogene Confidential Information in any Patent Rights that it files, or in connection with the prosecution of any such Patent Rights, without Allogene's prior written consent. Cellectis will notify Allogene promptly upon filing or otherwise obtaining rights in any Patent Right after the Effective Date that covers or may cover the Development, Manufacture, Commercialization or use of any Allogene Licensed Product. In the absence of such prompt notification, any such Patent Rights will be excluded from the Valid Claim definition. Cellectis will keep Allogene informed regarding each Patent Right included in the Licensed Intellectual Property that Cellectis or any Third Party licensor is prosecuting and will consider in good faith any recommendations made by Allogene in regard to the filing, prosecution or maintenance of any such Patent Right. To the extent Cellectis wishes not to file, prosecute or maintain any such Patent Right (other than any such Patent Right owned or co-owned by a Third Party licensor), Cellectis will provide Allogene with thirty (30) days prior written notice to such effect, in which event Allogene may elect to continue filing, prosecution or maintenance of such Patent Right, and Cellectis, upon Allogene's written request received within such thirty (30) day period, will execute such documents and perform such acts, at Allogene's expense, as may be reasonably necessary to permit Allogene to file, prosecute and maintain, at its own discretion, such Patent Right. Any such Patent Rights that are prosecuted or maintained by Allogene pursuant to this Section 6.2.1(c) will continue to be owned by Cellectis, and will be excluded from the Valid Claim definition; and, in addition to the exclusive licenses granted to Allogene under Section 4.1, Cellectis will and does hereby grant to Allogene (subject to any existing Third Party rights) a non-exclusive, sublicensable, perpetual, irrevocable, royalty-free, fully paid-up, worldwide license to practice and exploit such Patent Rights for any and all purposes. Cellectis will not decline to pay for or participate in the filing, prosecution or maintenance of any Patent Right under any Cellectis Third Party Agreement that is included in the Licensed Intellectual Property without Allogene's prior written consent.

(d) **Joint Patent Rights**. In the event the Parties conceive or generate any Joint Developed IP, other than any Joint Developed IP that constitutes Allogene CAR-T Developed IP, or Cellectis CAR-T Developed IP, the Parties will promptly meet to discuss and determine, based on mutual consent, whether to seek patent protection thereon. Neither Party will file any Patent Right covering or claiming any such Joint Developed IP (a "**Joint Patent Right**") Allogene will have the first right to file on and control prosecution of any Patent Right covering or claiming any Joint Developed IP used in the development, manufacture, composition or use of any CAR-T Targeting such Allogene Target in accordance with Section 6.2.1(b). For avoidance of doubt, "prosecution" as used in this Section 6.2.1 includes oppositions, nullity or revocation actions, post-grant reviews and other patent office proceedings involving the referenced Patent Rights.

(e) **Liability**. To the extent that a Party is obtaining, prosecuting or maintaining a Patent Right included in the Licensed Intellectual Property or Developed IP (including CAR-T Developed IP) or otherwise exercising its rights under this Section 6.2.1, such Party, and its Affiliates, employees, agents or representatives, will not be liable to the other Party in respect of any act, omission, default or neglect on the part of any such Party, or its Affiliates, employees, agents or representatives, in connection with such activities undertaken in good faith.

(f) **Extensions**. The decision to file for a patent term extension and particulars thereof (including which patent(s) to extend) will be made with the goal of obtaining the optimal patent term and scope of protection for Allogene Licensed Products. Allogene will have the sole right but not the obligation to apply for and obtain any patent term extension or related extension of rights, including supplementary protection certificates and similar rights, for any patent relating to an Allogene Licensed Product (including the choice of which patent(s) to extend), provided that it will consult with Cellectis before applying for or obtaining any such extensions or rights for any patents included in the Licensed Cellectis Intellectual Property. The Parties will provide reasonable assistance to each other in connection with obtaining any such extensions for any patent included in the Licensed Cellectis Intellectual Property. To the extent reasonably and legally required in order to obtain any such extension in a particular country, each Party will make available to the other a copy of the necessary documentation to enable such other Party to use the same for the purpose of obtaining the extension in such country.

(g) **Joint Research Agreement**. This Agreement will be understood to be a joint research agreement under 35 U.S.C. § 103(c)(3) entered into for the purpose of researching, identifying and Developing Agreement CAR-Ts and Allogene Licensed Products.

(h) **Recording**. If a Party deems it necessary or desirable to register or record this Agreement or evidence of this Agreement with any patent office or other appropriate government authorities in one or more jurisdictions in the Territory, then the Parties will agree on a proposed evidence of such recording and the Parties will comply with the terms of Section 7.2.3 in respect of such filing. Each Party will execute and deliver to the other Party any documents necessary or desirable to complete such registration or recordation in accordance with the terms of Section 7.2.3.

6.2.2. **Enforcement of Patent Rights**.

(a) **Notice**. If either Allogene or Cellectis becomes aware of any infringement that may affect competition of either Party within the Field, anywhere in the world, of any issued Patent Right within the Licensed Intellectual Property or Developed IP, such Party will promptly notify the other Party in writing to that effect.

(b) **Infringement of Certain Patent Rights.**

(i) Subject to the terms and conditions of any applicable Cellectis Third Party Agreements, if any infringement of a Patent Right included in the Licensed Intellectual Property by a Third Party arises from the Development, Manufacture or Commercialization of a product that does, or may, compete with an Allogene Licensed Product Targeting such Allogene Target, Allogene will have the first right, but not the obligation, to take action to obtain a discontinuance of infringement or bring suit against a Third Party infringer of such Patent Right within six (6) months from the date of notice and to join Cellectis as a party plaintiff in each of the following circumstances: (x) where the Allogene Licensed Product with which the Third Party's infringement will compete has been [***] or is the subject of [***] and no Cellectis Product or CAR-T product of another Cellectis licensee has begun or completed [***], or (y) where such Patent Right is directed exclusively to an Allogene

Target or an Allogene Licensed Product Targeting such Allogene Target or an Allogene Licensed Product Targeting such Allogene Target; in all other circumstances, Allogene may, with prior written consent of Cellectis (not to be unreasonably withheld), have the right to take action against such Third Party infringer.

(ii) Allogene will bear all the expenses of any suit brought by it claiming infringement of any such Patent Right. Cellectis will cooperate with Allogene in any such suit and will have the right to consult with Allogene and to participate in and be represented by independent counsel in such litigation at its own expense. Allogene will incur no liability to Cellectis as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding any such Patent Right invalid or unenforceable, and Allogene will not, without Cellectis' prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Cellectis or admits the invalidity or unenforceability of any such Patent Right.

(iii) If Allogene has not obtained a discontinuance of infringement by, or filed suit against, any such Third Party infringer within the six (6) month period set forth in subsection (i) above, then Cellectis will have the right, but not the obligation, to bring suit against such Third Party infringer, at Cellectis' sole expense; provided, however, that Cellectis will only have the foregoing right if Allogene would not be required (by Applicable Law or otherwise) to join such suit as a party and such suit would not involve a Patent Right covering a then-existing Agreement CAR-T or Allogene Licensed Product. Allogene will have no obligation to cooperate with Cellectis in any such litigation, provided that Allogene may, at its sole discretion, elect to consult with Cellectis and to participate in and be represented by independent counsel in such litigation at its own expense. Cellectis will incur no liability to Allogene as a consequence of such litigation or any unfavorable decision resulting therefrom, including any decision holding any such Cellectis Patent Right or Joint Patent Right invalid or unenforceable; and Cellectis will not, without Allogene's prior written consent, enter into any settlement or consent decree that requires any payment by or admits or imparts any other liability to Allogene or admits the invalidity or unenforceability of any such Patent Right.

(iv) The enforcing Party will keep the other Party reasonably informed of all material developments in connection with any such suit. Subject to the terms and conditions of any applicable Cellectis Third Party Agreements, any recoveries obtained by either Party as a result of any proceeding against such a Third Party infringer will be allocated as follows:

(A) Such recovery will first be used to reimburse each Party for all out-of-pocket litigation costs in connection with such litigation paid by that Party; and

(B) With respect to any remaining portion of such recovery, if Allogene was the enforcing Party, Cellectis will receive an amount equal to the royalty that would be payable, pursuant to Section 5.2, on an amount of Net Sales of the relevant Allogene Licensed Product(s) in the country(ies) where such infringement occurred equal to such remaining portion of such recovery, and Allogene will receive any remaining portion of such recovery; or

(C) With respect to any remaining portion of such recovery, if Cellectis was the enforcing Party, Cellectis will receive any remaining portion of such recovery, except to the extent such recovery was calculated based on lost sales of Allogene, in which case the allocation of such remaining portion will be made as provided in Section 6.2.2(b)(iv)(B).

(c) **Other Infringement of Joint Patent Rights**. With respect to any notice of a Third Party infringer of any Joint Patent Right other than in the case of a Joint Patent Right subject to Section 6.2.2(b), the Parties will meet as soon as reasonably practicable to discuss such infringement and determine an appropriate course of action and the Parties' respective rights and responsibilities with respect to any enforcement thereof.

6.2.3. **Biosimilar Notices.**

(a) **General Strategy.** Upon Allogene's request any time after completion of the first Phase II Clinical Trial for any Allogene Licensed Product, Cellectis will use reasonable efforts to assist and cooperate with Allogene in establishing a strategy for responding to requests for information from Regulatory Authorities and Third Party requestors and preparing submissions responsive to any Biosimilar Notices received by Allogene; provided that Allogene will make the final decisions with respect to such strategy and any such responses.

(b) **Biosimilar Notices**. Allogene will comply with the applicable provisions of 42 U.S.C. § 262(l) (or any amendment or successor statute thereto), any similar statutory or regulatory requirement enacted in the future regarding biologic products in the United States, or any similar statutory or regulatory requirement in any non-U.S. country or other regulatory jurisdiction, in each case, with respect to any Biosimilar Notice received by Allogene from any Third Party regarding any Allogene Licensed Product that is being Commercialized in the applicable jurisdiction, and the exchange of information between any Third Party and Allogene pursuant to such requirements; provided that, prior to any submission of information by Allogene to a Third Party, Cellectis will have the right to review the patent information included in such proposed submission, solely with respect to Patent Rights Controlled by Cellectis, and to make suggestions as to any changes to such patent information that Cellectis reasonably believes to be necessary; provided further that Allogene will determine the final content of any such submission. In the case of an Allogene Licensed Product approved in the United States under the PHS Act (or, in the case of a country in the Territory other than the United States, any similar law), to the extent permitted by Applicable Law, Allogene, as the sponsor of the application for the Allogene Licensed Product, will be the "reference product sponsor" under the PHS Act. Allogene will give written notice to Cellectis of receipt of a Biosimilar Notice received by Allogene with respect to an

Allogene Licensed Product, and Allogene will consult with Cellectis with respect to the selection of the Patent Rights to be submitted pursuant to 42 U.S.C. § 262(l) (or any similar law in any country of the Territory outside the United States); provided that Allogene will have final say on such selection of Patent Rights. Cellectis agrees to be bound by the confidentiality provisions of 42 U.S.C. § 262(l)(1)(B)(iii). In order to establish standing in connection with any action brought by Allogene under this Section 6.2.3, Cellectis, upon Allogene's request, will reasonably cooperate with Allogene in any such action, including timely commencing or joining in any action brought by Allogene under this Section 6.2.3 solely to the extent any Patent Rights Controlled by Cellectis are involved in any such action, and the Parties rights and responsibilities regarding any action will be determined in accordance with Section 6.2.2(b).

6.3. **Interference, Opposition, Revocation and Declaratory Judgment Actions**. If the Parties mutually determine that, based upon the review of a Third Party's patent or patent application or other intellectual property rights, it may be desirable in connection with any Agreement CAR-T or Allogene Licensed Product to provoke or institute an interference, opposition, revocation, post-grant review or other patent office proceedings or declaratory judgment action with respect thereto, then the Parties will consult with one another and will [***] in connection with such an action. Unless otherwise mutually determined by the Parties, Allogene will control such action and will select counsel for such action. The rights and obligations of the Parties under Section 6.4 are expressly subject to this Section 6.3.

6.4. **Infringement of Third Party Patent Rights**. If the Development, Manufacture or Commercialization of any Allogene Licensed Product is alleged by a Third Party to infringe a Third Party's patent or other intellectual property rights, the Party becoming aware of such allegation will promptly notify the other Party. The Party that is alleged to infringe the Third Party's patent or intellectual property rights will have the right to take such action as it deems appropriate in response to such allegation, and will be solely responsible for all damages, costs and expenses in connection therewith, subject to Section 10.1.

7. CONFIDENTIALITY

7.1. **Confidentiality**. Except to the extent expressly authorized by this Agreement, the Parties agree that, during the Term and [***], each Party (the "**Receiving Party**") receiving any Confidential Information of the other Party (the "**Disclosing Party**") hereunder will: (a) keep the Disclosing Party's Confidential Information confidential; (b) not disclose, or permit the disclosure of, the Disclosing Party's Confidential Information; and (c) not use, or permit to be used, the Disclosing Party's Confidential Information for any purpose, provided, however, that a Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such Confidential Information (i) was already known by the Receiving Party (other than under an obligation of confidentiality to the Disclosing Party) at the time of disclosure by the Disclosing Party; (ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party; (iii) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party, other than through any act or omission of the Receiving Party in breach of its obligations under this Agreement; (iv) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to the Receiving Party; or (v) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information of the Disclosing Party.

7.2. **Authorized Disclosure**.

7.2.1. **Disclosure to Party Representatives**. Notwithstanding the foregoing provisions of Section 7.1, the Receiving Party may disclose Confidential Information belonging to the Disclosing Party to the Receiving Party's, its Affiliates' and its Sublicensees' officers, directors, employees, consultants, contractors, licensors and agents (collectively, "**Representatives**") who (a) have a need to know such Confidential Information in connection with the performance of the Receiving Party's obligations or the exercise of the Receiving Party's rights under this Agreement and (b) have agreed in writing to non-disclosure and non-use provisions with respect to such Confidential Information that are at least as restrictive as those set forth in this Article 7.

7.2.2. **Disclosure to Third Parties**.

(a) Notwithstanding the foregoing provisions of Section 7.1, the Parties may disclose Confidential Information belonging to the other Party:

(i) to Governmental Authorities (A) to the extent reasonably necessary to obtain or maintain INDs or Regulatory Approvals for any Agreement CAR-T or Allogene Licensed Product Targeting such Allogene Target, or any Cellectis Target or Cellectis Product Targeting such Cellectis Target, within the Territory, and (B) in order to respond to inquiries, requests, investigations, orders or subpoenas relating to this Agreement;

(ii) to outside consultants, contractors, advisory boards, managed care organizations, and non-clinical and clinical investigators, in each case to the extent reasonably necessary for the performance of this Agreement and under reasonable obligations of confidentiality;

(iii) to the extent reasonably necessary, in connection with filing or prosecuting Patent Rights or Trademark rights as permitted by this Agreement;

(iv) to the extent reasonably necessary, in connection with prosecuting or defending litigation as permitted by this Agreement;

(v) subject to Section 7.3.2, in connection with or included in scientific presentations and publications relating to Agreement CAR-Ts or Allogene Licensed Products, including abstracts, posters, journal articles and the like, and posting results of and other information about clinical trials to clincialtrials.gov or PhRMA websites; and

(vi) to the extent necessary in order to enforce its rights under this Agreement and as permitted in the Agreement.

(b) In the event a Party deems it reasonably necessary to disclose Confidential Information belonging to the other Party pursuant to Section 7.2.2(a)(i)(B), the Disclosing Party will to the extent possible give reasonable advance written notice of such disclosure to the other Party and take all reasonable measures to ensure confidential treatment of such information.

7.2.3. **SEC Filings and Other Disclosures**. Notwithstanding any provision of this Agreement to the contrary, either Party may disclose the terms of this Agreement to the extent required, in the reasonable opinion of such Party's legal counsel, to comply with applicable Law, including the rules and regulations promulgated by the United States Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory. Notwithstanding the foregoing, before disclosing this Agreement or any of the terms hereof pursuant to this Section 7.2.3, the Parties will consult with one another on the terms of this Agreement to be redacted in making any such disclosure. Further, if a Party discloses this Agreement or any of the terms hereof in accordance with this Section 7.2.3, such Party will, at its own expense, seek such confidential treatment of confidential portions of this Agreement and such other terms, as may be reasonably requested by the other Party.

7.3. **Public Announcements; Publications**.

7.3.1. **Announcements**. Except as may be expressly permitted under Section 7.2.3, neither Party will make any public announcement regarding this Agreement without the prior written approval of the other Party. For the sake of clarity, nothing in this Agreement will prevent (a) either Party from making any public disclosure relating to this Agreement if the contents of such public disclosure have previously been made public other than through a breach of this Agreement by the issuing Party or its Affiliates; (b) Allogene from making any scientific publication or public announcement with respect to any Allogene Licensed Product Targeting such Allogene Target under this Agreement; provided, however, that, except as permitted under Section 7.2, Allogene will not disclose any of Cellectis' Confidential Information in any such publication or announcement without obtaining Cellectis' prior written consent to do so and (c) Cellectis from making any scientific publication or public announcement with respect to any Cellectis Licensed Product Targeting such Cellectis Program Target under this Agreement; provided, however, that, except as permitted under Section 7.2, Cellectis will not disclose any of Allogene's Confidential Information in any such publication or announcement without obtaining Allogene's prior written consent to do so.

7.3.2. **Publications**. During the Term, each Party will submit to the other Party (the "**Non-Disclosing Party**") for review and approval any proposed academic, scientific and medical publication or public presentation which contains the Non-Disclosing Party's Confidential Information. In addition, each Party will submit to the other Party for its review and approval any proposed publication or public presentation relating to the Research Program. In both instances, such review and approval will be conducted for the purposes of preserving the value of the Licensed Intellectual Property, Cellectis CAR-T Developed IP and Allogene CAR-T Developed IP and the rights granted to each Party hereunder and determining whether any portion of the proposed publication or presentation containing the Non-Disclosing Party's Confidential Information should be modified or deleted. Written copies of such proposed publication or presentation required to be submitted hereunder will be submitted to the Non-Disclosing Party no later than thirty (30) days before submission for publication or presentation (the "**Review Period**"). The Non-Disclosing Party will provide its comments with respect to such publications and presentations within twenty (20) days after its receipt of such written copy, and the other Party will delete any Confidential Information of the Non-Disclosing Party upon request. The Review Period may be extended for an additional sixty (60) days in the event the Non-Disclosing Party can, within fifteen (15) days of receipt of the written copy, demonstrate reasonable need for such extension, including for the preparation and filing of patent applications. Cellectis and Allogene will each comply with standard academic practice regarding authorship of scientific publications and recognition of contribution of other parties in any publication governed by this Section 7.3.2.

7.4. **Obligations in Connection with Change of Control**. If Cellectis is subject to a Change of Control, Cellectis will, and it will cause its Affiliates and Representatives to, ensure that no Confidential Information of Allogene is released to (a) any Affiliate of Cellectis that becomes an Affiliate as a result of the Change of Control or (b) any Representatives of Cellectis (or of the relevant surviving entity of such Change of Control) who become Representatives as a result of the Change of Control, unless such Representatives have signed individual confidentiality agreements which include equivalent obligations to those set out in this Article 7. If any Change of Control of Cellectis occurs, Cellectis will promptly notify Allogene, share with Allogene the policies and procedures it plans to implement in order to protect the confidentiality of Allogene's Confidential Information prior to such implementation and make any adjustments to such policies and procedures that are reasonably requested by Allogene.

8. REPRESENTATIONS AND WARRANTIES.

8.1. **Mutual Representations and Warranties**. Each of Cellectis and Allogene hereby represents and warrants to the other Party that:

8.1.1. it is duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization;

8.1.2. the execution, delivery and performance of this Agreement by such Party has been duly authorized by all requisite action under the provisions of its charter, bylaws and other organizational documents, and does not require any action or approval by any of its shareholders or other holders of its voting securities or voting interests;

8.1.3. it has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder;

8.1.4. this Agreement has been duly executed and is a legal, valid and Binding Obligation on each Party, enforceable against such Party in accordance with its terms; and

8.1.5. the execution, delivery and performance by such Party of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of or default under any Binding Obligation existing as of the Effective Date.

8.2. **Representations and Warranties of Cellectis**. Cellectis hereby represents and warrants to Allogene that:

8.2.1. it has and will have the full right, power and authority to grant all of the right, title and interest in the licenses and other rights granted or to be granted to Allogene or Allogene's Affiliates under this Agreement;

8.3. **Representations and Warranties of Allogene**. Allogene hereby represents and warrants to Cellectis that:

8.3.1. it has and will have the full right, power and authority to grant all of the right, title and interest in the licenses and other rights granted or to be granted to Cellectis or Cellectis's Affiliates under this Agreement.

8.4. **Mutual Covenants**. In addition to the covenants made by the Parties elsewhere in this Agreement, each Party hereby covenants to the other that, from the Effective Date until expiration or termination of this Agreement:

8.4.1. it will not (a) take any action that diminishes the rights under the Licensed Cellectis Intellectual Property or Licensed Allogene Intellectual Property or Developed IP granted or assigned under this Agreement or (b) fail to take any action that is reasonably necessary to avoid diminishing the rights under the Licensed Cellectis Intellectual Property, Licensed Allogene Intellectual Property or Developed IP granted or assigned to Allogene or Allogene's Affiliates under this Agreement;

8.4.2. it will (a) not enter into any Third Party Agreement that adversely affects (i) the rights granted to the other Party hereunder or (ii) its ability to fully perform its obligations hereunder; (b) not amend, terminate or otherwise modify any Third Party Agreement (including for Cellectis, the Servier Agreement) or consent or waive rights with respect thereto in any manner that (i) adversely affects the rights granted to the other Party hereunder or (ii) its ability to fully perform its obligations hereunder; (c) fulfill, and cause its Affiliates to fulfill, all of their respective obligations under all Third Party Agreements (including for Cellectis Servier Agreements) so as not to be in breach of such agreements; (d) inform Allogene of existence of all notices received by Cellectis or its Affiliates relating to any alleged breach or default by Cellectis or its Affiliates under any Third Party Agreement (including Servier Agreement), and all other notices received by Cellectis or its Affiliates in connection with any Cellectis Third Party Agreement that pertain to the rights granted to Allogene or Allogene's Affiliates hereunder, within [***] after receipt thereof; and (e) in the event that Cellectis does not resolve any such alleged breach or default, notify Allogene within a sufficient period of time before the expiration of the cure period for such breach of default under such Cellectis Third Party Agreement such that Allogene is able to cure or otherwise resolve such alleged breach or default, and if Allogene makes any payments to any Third Party in connection with the cure or other resolution of such alleged breach or default, then Allogene may credit the amount of such payments against any royalties or other amounts payable to Cellectis pursuant to this Agreement.

8.4.3. It will perform and discharge its obligations under this Agreement in conformance with Applicable Laws.

8.4.4. it will not enter into or otherwise allow itself or its Affiliates to be subject to any agreement or arrangement which limits the ownership rights of the other Party or its Affiliates with respect to, or limits the ability of the other Party or its Affiliates to grant a license, sublicense or access, or provide or provide access or other rights in, to or under, any intellectual property right or material (including any Patent Right, Know-How or other data or information), in each case, that would, but for such agreement or arrangement, be included in the rights licensed or assigned to the other Party or its Affiliates pursuant to this Agreement; and

8.4.5. it shall not, and shall not permit any of its subsidiaries and Affiliates or any of its or their respective directors, officers, managers, employees, independent contractors, representatives or agents (collectively, "**Reps**") to, promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, any non-U.S. government official, in each case, in violation of the U.S. Foreign Corrupt Practices Act, as amended ("**FCPA**") or any other applicable anti-bribery or anti-corruption law.

8.4.6. it shall, and shall cause each of its subsidiaries and Affiliates to, cease all of its or their respective activities, as well as remediate any actions taken by it, its subsidiaries or Affiliates or any of its or their respective Reps in violation of the FCPA or any other applicable anti-bribery or anti-corruption law.

8.4.7. it shall, and shall cause each of its Affiliates and subsidiaries to, maintain systems or internal controls (including, but not limited to, accounting systems, purchasing systems and billing systems) to ensure compliance with the FCPA or any other applicable anti-bribery or anti-corruption law.

8.5. **Representation by Legal Counsel**. Each Party hereto represents that it has been represented by legal counsel in connection with this Agreement and acknowledges that it has participated in the drafting hereof. In interpreting and applying the terms and provisions of this Agreement, the Parties agree that no presumption will exist or be implied against the Party which drafted such terms and provisions.

8.6. **Disclaimer**. THE FOREGOING REPRESENTATIONS AND WARRANTIES OF EACH PARTY ARE IN LIEU OF ANY OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR ANY IMPLIED WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE, ALL OF WHICH ARE HEREBY SPECIFICALLY EXCLUDED AND DISCLAIMED.

9. GOVERNMENT APPROVALS; TERM AND TERMINATION.

9.1. **Government Approvals**. Each of Cellectis and Allogene will cooperate with the other Party and use Commercially Reasonable Efforts to make all registrations, filings and applications, to give all notices and to obtain as soon as practicable all governmental or other consents, transfers, approvals, orders, qualifications authorizations, permits and waivers, if any, and to do all other things necessary or desirable for the consummation of the transactions as contemplated hereby.

9.2. **Term**. The term of this Agreement (the "**Term**") will commence on the Effective Date and will extend, unless this Agreement is terminated earlier in accordance with this Article 9, on an Allogene Licensed Product-by-Allogene Licensed Product and country-by-country basis, until such time as the Royalty Term with respect to the sale of such Allogene Licensed Product in such country expires.

9.3. **Termination by Either Party for Cause**. Either Party may terminate this Agreement, in its entirety or, at the terminating Party's option, on an Allogene Target-by-Allogene Target basis or Cellectis Program Target-by Cellectis Program Target basis, as applicable, at any time during the Term of this Agreement by giving written notice to the other Party if the other Party commits a material breach of its obligations under this Agreement and such breach remains uncured for ninety (90) days, measured from the date written notice of such breach is given to the breaching Party. Notwithstanding the foregoing, a Party will have the right to terminate this Agreement pursuant to this Section 9.3: (a) in part with respect to an individual Allogene Target or Cellectis Program Target, as applicable, only if the other Party's material breach giving rise to such termination right relates to such Allogene Target or Cellectis Program Target, as applicable, or (b) in its entirety only if such material breach fundamentally frustrates the objectives or transactions contemplated by this Agreement taken as a whole.

9.4. **Termination by Allogene for Convenience**. Allogene will have the right to terminate this Agreement for any or no reason, either in its entirety or on an Allogene Target-by-Allogene Target basis, by providing sixty (60) days advance written notice of such termination to Cellectis.

9.5. **Termination on Insolvency of Cellectis**. This Agreement may be terminated upon written notice by Allogene at any time in the event of a Cellectis Insolvency Event.

9.6. **Effects of Termination**.

9.6.1. **Effect of Termination by Allogene for Cause**. If Allogene terminates this Agreement with respect to any or all Allogene Targets pursuant to Section 9.3 (each, a "**Terminated Target**"):

(a) all licenses granted to Allogene with respect to such Terminated Target and any Allogene Licensed Product Targeting such Terminated Target (each, a "**Terminated Allogene Licensed Product**"), including under Section 4.1, will continue and become irrevocable and perpetual, and Allogene will have no further obligations to Cellectis under this Agreement with respect to any such Terminated Target or Terminated Allogene Licensed Product (including no further obligation to pay Milestone Payments) other than (i) those obligations that expressly survive termination in accordance with Section 9.8 and (ii) an obligation to pay royalties with respect to Net Sales of Terminated Allogene Licensed Products in accordance with the terms and conditions of this Agreement, in an amount equal to [***] of the amount that would otherwise have been payable under this Agreement;

(b) If Allogene terminates this Agreement in its entirety pursuant to Section 9.3, or if Allogene terminates this Agreement in its entirety pursuant to Section 9.4: (i) all licenses granted by Allogene to Cellectis under Sections 4.2.1 and 4.2.2 will terminate, (ii) Allogene will have no further obligations to Cellectis under this Agreement other than those obligations that expressly survive termination in accordance with Section 9.8, and (iii) any material or Confidential Information provided Allogene to Cellectis in the course of the performance of this Agreement will be returned or destroyed as directed in writing by Allogene;

(c) Allogene will have the right to offset, against any payment owing to Cellectis under subparagraph (b) above, any damages found or agreed by the Parties to be owed by Cellectis to Allogene;

(d) Cellectis will remain entitled to receive payments that accrued before the effective date of such termination;

(e) nothing in this Section 9.6.1 will limit any other remedy Allogene may have for Cellectis' breach of this Agreement; and

(f) the rights and obligations of the Parties with respect to all Allogene Targets other than any such Terminated Target will remain in full force and effect.

9.6.2. **Effect of Termination by Allogene on Insolvency of Cellectis**. If Allogene terminates this Agreement pursuant to Section 9.5:

(a) Cellectis will have no further obligation to perform any of its obligations under this Agreement other than those obligations that expressly survive termination of this Agreement in accordance with Sections 9.6.2(b) and 9.8;

(b) all licenses granted to Allogene, including under Section 4.1, will continue and become, subject only to the royalty obligation set forth below in this Section 9.6.2(b), irrevocable and perpetual, and Allogene will have no further obligations to Cellectis under this Agreement (including no further obligation to pay Milestone Payments) other than (i) those obligations that expressly survive termination in accordance with Section 9.8 and (ii) an obligation to pay royalties with respect to Net Sales of Allogene Licensed Products in accordance with the terms and conditions of this Agreement;

(c) Cellectis will remain entitled to receive payments that accrued before the effective date of such termination;

(d) Allogene will have the right to offset, against any payment owing to Cellectis under subparagraph (b) above, any damages found or agreed by the Parties to be owed by Cellectis to Allogene; and

(e) nothing in this Section 9.6.2 will limit any other remedy Allogene may have for Cellectis' breach of this Agreement.

9.6.3. **Effect of Termination by Cellectis for Cause or by Allogene for Convenience**.

(a) If Cellectis terminates this Agreement with respect to any Allogene Target pursuant to Section 9.3, or if Allogene terminates this Agreement with respect to any Allogene Target pursuant to Section 9.4, then (i) all licenses granted by Cellectis to Allogene under Sections 4.1.1, 4.1.2 and 4.1.3 with respect to any such Allogene Target will terminate, (ii) any Allogene Licensed Product Targeting such Allogene Target will terminate, and (iii) any material or Confidential Information provided by Cellectis to Allogene in the course of the performance of this Agreement will be returned or destroyed as directed in writing by Cellectis.

(b) If Cellectis terminates this Agreement in its entirety pursuant to Section 9.3, or if Allogene terminates this Agreement in its entirety pursuant to Section 9.4: (i) all licenses granted by Cellectis to Allogene under Sections 4.1.1, 4.1.2 and 4.1.3 will terminate, (ii) all rights and licenses granted by Cellectis to Allogene pursuant to Section 4.1.2(b) and 4.1.2(d), and all obligations to which the parties are bound hereunder with relation thereto, will continue in full force and effect, to the extent such rights and licenses were not previously or concurrently terminated (including as set forth in Section 9.6.3(a) herein) and will subsequently terminate in accordance with the terms of the Servier Agreement, wherein such rights and licenses were initially granted to Servier, (iii) Cellectis will have no further obligations to Allogene under this Agreement other than those obligations that expressly survive termination in accordance with Section 9.8, (iv) all rights and licenses granted by Allogene to Cellectis pursuant to Section 4.2 will continue, (v) Allogene's right of first refusal set forth in Section 3.6 will continue to the extent that such Cellectis Product is Covered by Licensed Allogene Intellectual Property and (vi) any material or Confidential Information provided by Cellectis to Allogene in the course of the performance of this Agreement will be returned or destroyed as directed in writing by Cellectis. For the avoidance of doubt, all rights and licenses granted by Cellectis to Allogene pursuant to Section 4.1.2(b) and 4.1.2(d), and all obligations to which the parties are bound hereunder with relation thereto, will terminate immediately upon the earlier to occur of (i) termination or expiration of the license granted by Cellectis to Servier in respect of the [***] Patent Rights for the Other Products pursuant to the Servier Agreement, or (ii) on an Other Product-by-Other Product basis, termination or expiration of the license granted by Servier to Allogene in respect of an Other Product pursuant to the Exclusive License and Collaboration Agreement dated as of October 30, 2015 by and between Allogene and Servier (as amended from time to time).

(c) In the event that Cellectis terminates this Agreement for cause pursuant to Section 9.3 or Allogene terminates this Agreement without cause pursuant to Section 9.4 with respect to an Allogene Licensed Product Targeting an Allogene Target, on Cellectis' written notice to Allogene, which notice may only be delivered within [***] following the effective date of such termination, unless such termination is related to material concerns regarding the safety of the Compound(s) or Product(s), the Parties will negotiate in good faith for a period not to exceed [***] following the effective date of termination regarding:

(i) the grant by Allogene to Cellectis of a royalty-bearing, non-exclusive license under the Applicable Allogene Technology permitting Cellectis to continue to Develop, Commercialize and Manufacture any Product under Development or Commercialization by Allogene under this Agreement at the time of termination, in the form in which such Product then exists (a "**Continuation Product**"); and

(ii) the related transfer to Cellectis of development data and regulatory filings specifically relating to such Continuation Product or the granting to Cellectis of rights of reference with respect to such data and filings.

(d) Neither Party will be obligated to enter into any transaction described in Section 9.6.3(c) and neither Party will have any liability to the other for failure to do so.

(e) For the avoidance of doubt, if Cellectis terminates this Agreement with respect to any Allogene Target pursuant to Section 9.3, or if Allogene terminates this Agreement with respect to any Allogene Target pursuant to Section 9.4, in each case including all Allogene Targets in the event that this Agreement is terminated in its entirety, any such Allogene Target will no longer be considered to be an Allogene Target for the purpose of this Agreement.

9.6.4. **Satisfaction of Obligations During Notice Period**. During the period from providing a notice of termination through the termination of the Agreement, the Parties will continue to perform their obligations under this Agreement.

9.6.5. **Pending Dispute Resolution**. If a Party gives notice of termination under Section 9.3 and the other Party disputes whether such notice was proper, then the issue of whether this Agreement has been terminated will be resolved in accordance with Section 11.10 and this Agreement will remain in effect pending the resolution of such dispute. If as a result of such dispute resolution process it is determined that the notice of termination was proper, then such termination will be effective immediately. If as a result of such dispute resolution process it is determined that the notice of termination was improper, then no termination will have occurred and this Agreement will remain in effect.

9.7. **Disposition of Inventories of Products**. Following termination of this Agreement with respect to one or more Allogene Targets, Allogene, its Affiliates and its Sublicensees will have the right to continue to sell their existing inventories of Allogene Licensed Product(s) Targeting such Allogene Targets that have received Regulatory Approval prior to such termination for a period not to exceed [***] after the effective date of such termination or expiration and Allogene will pay any royalties payable in connection with such sales in accordance with Section 5.2.

9.8. **Survival of Certain Obligations.** Expiration or termination of this Agreement will not relieve the Parties of any obligation that accrued before such expiration or termination. The following provisions will survive expiration or termination of this Agreement: Sections 1(Definitions); 5.4.2 to 5.4.6 (Reports and Payments); 5.5 (Maintenance and Audit Rights); 7 (Confidentiality); 8 (Representations and Warranties); 9.3 to 9.8 (Effect of Termination); 10 (Limitation on liabilities) and 11 (Miscellaneous). In addition, any Section that is referred to in the above listed Sections shall survive solely for the interpretation or enforcement of the listed Sections.

9.9. **Right to Terminate this Agreement by Allogene upon Change of Control of Cellectis**. If a Change of Control of Cellectis is consummated during the Term of this Agreement, Allogene will have the right to terminate this Agreement in its entirety, upon written notice to Cellectis within sixty (60) days after consummation of such Change of Control of Cellectis.

9.10. **Bankruptcy**. All rights and licenses granted under or pursuant to this Agreement by Cellectis are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Allogene, as licensee of intellectual property under this Agreement, will retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that in the event of a rejection of this Agreement by Cellectis in any bankruptcy proceeding by or against Cellectis under the U.S. Bankruptcy Code, (i) Allogene will be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Allogene's possession, will be promptly delivered to it upon Allogene's written request therefor, and (ii) Cellectis will not interfere with Allogene's rights to intellectual property and all embodiments of intellectual property, and will assist and not interfere with Allogene in obtaining intellectual property and all embodiments of intellectual property from another entity. The term "embodiments" of intellectual property includes all tangible, intangible, electronic or other embodiments of rights and licenses hereunder, including all compounds and products embodying intellectual property, Allogene Licensed Products, filings with Regulatory Authorities and related rights, and Cellectis Technology.

10. LIMITATION ON LIABILITY, INDEMNIFICATION AND INSURANCE.

10.1. **No Consequential Damages**. Except with respect to liability arising from a breach of Article 7, from any willful misconduct or intentionally wrongful act, or to the extent such Party may be required to provide indemnification under this Article 10, in no event will either Party, its Affiliates, its Sublicensees or any of its, its Affiliates' or its Sublicensees' respective Representatives be liable under this Agreement for any special, indirect, incidental, consequential or punitive damages, whether in contract, warranty, tort, negligence, strict liability or otherwise, including loss of profits or revenue suffered by either Party or any of its respective Affiliates or Representatives. Without limiting the generality of the foregoing, "consequential damages" will be deemed to include, and neither Party will be liable to the other Party or any of such other Party's Affiliates, Representatives or stockholders for, any damages based on or measured by loss of projected or speculative future sales of the Allogene Licensed Products, any Milestone Payment due upon any unachieved event under Section 5.1, any unearned royalties under Section 5.2 or any other unearned, speculative or otherwise contingent payments provided for in this Agreement.

10.2. **Indemnification by Allogene**. Allogene will indemnify, defend and hold harmless Cellectis, its Affiliates, their sublicensees, contractors, subcontractors and distributors and each of its and their respective employees, officers, directors and agents (each, a "**Cellectis Indemnified Party**") from and against any and all liability, loss, damage, expense (including reasonable attorneys' fees and expenses) and cost (collectively, a "**Liability**") that the Cellectis Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

10.2.1. [***]

10.2.2. [***]

[***]

10.3. **Indemnification by Cellectis**. Cellectis will indemnify, defend and hold harmless Allogene, its Affiliates, Sublicensees, contractors, distributors and each of its and their respective employees, officers, directors and agents (each, a "**Allogene Indemnified Party**") from and against any and all Liabilities that the Allogene Indemnified Party may be required to pay to one or more Third Parties resulting from or arising out of:

10.3.1. [***]

10.3.2. [***]

[***]

10.4. **Procedure**.

10.4.1. **Notice**. Each Party will notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In the event that any Third Party asserts a claim or other proceeding (including any governmental investigation) with respect to any matter for which a Party (the "**Indemnified Party**") is entitled to indemnification hereunder (a "**Third Party Claim**"), then the Indemnified Party will promptly notify the Party obligated to indemnify the Indemnified Party (the "**Indemnifying Party**") thereof; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation hereunder unless (and then only to the extent that) the Indemnifying Party is prejudiced thereby.

10.4.2. **Control**. Subject to Allogene's right to control any actions described in Section 6.2 (even where Cellectis is the Indemnifying Party), the Indemnifying Party will have the right, exercisable by notice to the Indemnified Party within ten (10) Business Days after receipt of notice from the Indemnified Party of the commencement of or assertion of any Third Party Claim, to assume direction and control of the defense, litigation, settlement, appeal or other disposition of the Third Party Claim (including the right to settle the claim solely for monetary consideration) with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party; provided that (a) the Indemnifying Party has sufficient financial resources, in the reasonable judgment of the Indemnified Party, to satisfy the amount of any adverse monetary judgment that is sought, (b) the Third Party Claim seeks solely monetary damages and (c) the Indemnifying Party expressly agrees in writing that as between the Indemnifying Party and the Indemnified Party, the Indemnifying Party will be solely obligated to satisfy and discharge the Third Party Claim in full (the conditions set forth in clauses (a), (b) and (c) above are collectively referred to as the "**Litigation Conditions**"). Within ten (10) Business Days after the Indemnifying Party has given notice to the Indemnified Party of its exercise of its right to defend a Third Party Claim, the Indemnified Party will give notice to the Indemnifying Party of any objection thereto based upon the Litigation Conditions. If the Indemnified Party reasonably so objects, the Indemnified Party will continue to defend the Third Party Claim, at the expense of the Indemnifying Party, until such time as such objection is withdrawn. If no such notice is given, or if any such objection is withdrawn, the Indemnifying Party will be entitled, at its sole cost and expense, to assume direction and control of such defense, with counsel selected by the Indemnifying Party and reasonably acceptable to the Indemnified Party. During such time as the Indemnifying Party is controlling the defense of such Third Party Claim, the Indemnified Party will cooperate,

and will cause its Affiliates and agents to cooperate upon request of the Indemnifying Party, in the defense or prosecution of the Third Party Claim, including by furnishing such records, information and testimony and attending such conferences, discovery proceedings, hearings, trials or appeals as may reasonably be requested by the Indemnifying Party. In the event that the Indemnifying Party does not satisfy the Litigation Conditions or does not notify the Indemnified Party of the Indemnifying Party's intent to defend any Third Party Claim within ten (10) Business Days after notice thereof, the Indemnified Party may (without further notice to the Indemnifying Party) undertake the defense thereof with counsel of its choice and at the Indemnifying Party's expense (including reasonable, out-of-pocket attorneys' fees and costs and expenses of enforcement or defense). The Indemnifying Party or the Indemnified Party, as the case may be, will have the right to join in (including the right to conduct discovery, interview and examine witnesses and participate in all settlement conferences), but not control, at its own expense, the defense of any Third Party Claim that the other Party is defending as provided in this Agreement.

10.4.3. **Settlement**. The Indemnifying Party will not, without the prior written consent of the Indemnified Party, enter into any compromise or settlement that commits the Indemnified Party to take, or to forbear to take, any action. The Indemnified Party will have the sole and exclusive right to settle any Third Party Claim, on such terms and conditions as it deems reasonably appropriate, to the extent such Third Party Claim involves equitable or other non-monetary relief, but will not have the right to settle such Third Party Claim to the extent such Third Party Claim involves monetary damages without the prior written consent of the Indemnifying Party. Each of the Indemnifying Party and the Indemnified Party will not make any admission of liability in respect of any Third Party Claim without the prior written consent of the other Party, and the Indemnified Party will use reasonable efforts to mitigate Liabilities arising from such Third Party Claim.

10.5. **Insurance**. Each Party will obtain and maintain, during the Term, commercial general liability insurance, including products liability insurance, with reputable and financially secure insurance carriers (or pursuant to a program of self-insurance reasonably satisfactory to the other Party) to cover its indemnification obligations under Section 10.2 or Section 10.3, as applicable, in each case with limits of not less than [***] per occurrence and in the aggregate.

11. MISCELLANEOUS.

11.1. **Other Cellectis Targets**. For sake of clarity, except as set forth in Schedule 1.86 and Section 3.7 (Right of Negotiation), Other Cellectis Targets are outside the scope of this Agreement.

11.2. **Assignment**. Either Party may not assign this Agreement or any interest hereunder without the prior written consent of the other, which consent will not be unreasonably withheld or delayed., except that this Agreement may be assigned as follows: (a) a Party may assign its rights and obligations under this Agreement by way of sale of itself or the sale of the portion of its business to which this Agreement relates, through merger, sale of assets or sale of stock or ownership interest and (b) a Party may assign its rights and obligations under this Agreement to any of its Affiliates. This Agreement will be binding upon the successors and permitted assigns of the Parties and the name of a Party appearing herein will be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 11.2 will be void.

11.3. **Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of the Agreement.

11.4. **Force Majeure**. Each Party will be excused from the performance of its obligations under this Agreement to the extent that such performance is prevented by force majeure (defined below) and the nonperforming Party promptly provides notice of the prevention to the other Party. Such excuse will be continued so long as the condition constituting force majeure continues and the nonperforming Party takes Commercially Reasonable Efforts to resume performance. For purposes of this Agreement, "force majeure" will include conditions beyond the control of the Parties, including an act of God, voluntary or involuntary compliance with any Applicable Law or order of any government, war, act of terror, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, or destruction of production facilities or materials by fire, earthquake, storm or like catastrophe.

11.5. **Notices**. Any notice or notification required or permitted to be provided pursuant to the terms and conditions of this Agreement (including any notice of force majeure, breach, termination, change of address, etc.) will be in writing and will be deemed given upon receipt if delivered personally or by facsimile or email transmission (receipt verified), five days after deposited in the mail if mailed by registered or certified mail (return receipt requested) postage prepaid, or on the next Business Day if sent by overnight delivery using a nationally recognized express courier service and specifying next Business Day delivery (receipt verified), to the Parties at the following addresses or facsimile numbers (or at such other address or facsimile number for a Party as will be specified by like notice, provided, however, that notices of a change of address will be effective only upon receipt thereof):

All correspondence to Allogene will be addressed as follows:

Allogene Therapeutics, Inc.
210 East Grand Avenue
South San Francisco, CA 94080
USA
Attention: General Counsel
Email: [***]

All correspondence to Cellectis will be addressed as follows:

Cellectis
8, rue de la Croix Jarry
75013 Paris
Attn.: Chief Executive Officer
Fax.: +33 1 81 69 16 03
Email: [***]

with a copy to:

Cellectis
8, rue de la Croix Jarry
75013 Paris
Attn.: General Counsel
Fax.: +33 1 81 69 16 03
Email: [***]

11.6. **Amendment**. No amendment, modification or supplement of any provision of this Agreement will be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

11.7. **Waiver**. No provision of this Agreement will be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party. The waiver by either of the Parties of any breach of any provision hereof by the other Party will not be construed to be a waiver of any succeeding breach of such provision or a waiver of the provision itself.

11.8. **Severability**. If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same will not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement will be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement will be construed as if such clause or portion thereof had never been contained in this Agreement, and there will be deemed substituted therefor such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by Applicable Law.

11.9. **Descriptive Headings**. The descriptive headings of this Agreement are for convenience only and will be of no force or effect in construing or interpreting any of the provisions of this Agreement.

11.10. **Dispute Resolution**. If any dispute or disagreement arises between Allogene and Cellectis in respect of this Agreement, they will follow the following procedures in an attempt to resolve the dispute or disagreement:

11.10.1. The Party claiming that such a dispute exists will give notice in writing (a "**Notice of Dispute**") to the other Party of the nature of the dispute.

11.10.2. Within [***] of receipt of a Notice of Dispute, the Allogene Alliance Manager and the Cellectis Alliance Manager will meet in person or by teleconference and exchange written summaries reflecting, in reasonable detail, the nature and extent of the dispute, and at this meeting they will use their reasonable endeavors to resolve the dispute.

11.10.3. If the Alliance Managers are unable to resolve the dispute during the meeting described in Section 11.10.2 or if for any reason such meeting does not take place within the period specified in Section 11.10.2, then the Chief Executive Officer of Allogene and the Chief Executive Officer of Cellectis will meet at a mutually agreed-upon time and location for the purpose of resolving such dispute.

11.10.4. If, within a further period of [***], or if in any event within [***] of initial receipt of the Notice of Dispute, the dispute has not been resolved, or if, for any reason, the meeting described in Section 11.10.3 has not been held within [***] of initial receipt of the Notice of Dispute, then the Parties agree that, subject to Section 11.11 below, either Party may initiate litigation to resolve the dispute.

11.11. **Election of Resolution Process**. Notwithstanding any provision of Section 11.10 to the contrary, if (i) either Party raises any allegation or claim of Misuse (each, a "**Misuse Allegation**") and (ii) the Parties are unable to resolve such Misuse Allegation pursuant to the dispute escalation process described in Sections 11.10.1 through 11.10.4 (the "**Escalation Process**"), then, following completion of the Escalation Process, the Parties may mutually agree to have such Misuse Allegation resolved pursuant to the terms of Section 11.12 (Arbitration Process). If the Parties fail to agree on use of arbitration pursuant to Section 11.12 in a timely manner (not to exceed [***]), then the Parties will be deemed to have elected to have such Misuse Allegation resolved through litigation.

11.12. **Arbitration Process**. If the Parties mutually elect to resolve any Misuse Allegation pursuant to this Section 11.12, then such Misuse Allegation will be referred to and finally resolved by binding arbitration in accordance with the Commercial Rules and Procedures (the "**Rules**") of the International Chamber of Commerce (the "**ICC**"), by an arbitral tribunal composed of three arbitrators, all of whom will have relevant experience in pharmaceutical industry, appointed by agreement of the Parties in accordance with the Rules. If, at the time of the arbitration, the Parties agree in writing to submit the dispute to a single arbitrator, said single arbitrator will (1) have relevant experience in pharmaceutical industry and (2) be appointed by agreement of the Parties, or, failing such agreement, by ICC in accordance with the Rules. The foregoing arbitration proceedings may be commenced by either Party by written notice to the other Party. Unless otherwise agreed by the Parties hereto, all such arbitration proceedings will be held in London, England, provided that proceedings may be conducted by telephone conference call with the consent of both Parties and the arbitrator(s). All arbitration proceedings will be conducted in the English language.

11.12.1. **Limited Discovery**. Documentary discovery may be conducted at the discretion of the arbitrator(s), provided that any such discovery will (a) be limited to documents directly relating to the Misuse Allegation, (b) be conducted pursuant to document discovery procedures as set forth under the laws of the State of New York, U.S.A., (c) be conducted subject to the schedule stipulated by the Parties, or in the absence of stipulation, the schedule ordered by the arbitrator(s), and (d) not require either Party, its Affiliates or their respective employees, officers, directors or agents to be subject to deposition. Notwithstanding any provision of this Section 11.12.1 to the contrary, all discovery must be completed within sixty (60) days of the notice of commencement of arbitration proceedings.

11.12.2. **Awards and Fees**. The arbitrator(s) may only consider awards of direct monetary damages and will not under any circumstances have the authority to grant (a) injunctive relief, (b) equitable relief, (c) orders for specific performance, (d) punitive damages or (e) consequential damages as described in Section 10.1. The allocation of expenses of the arbitration, including reasonable attorney's fees, will be determined by the arbitrator(s), or, in the absence of such determination, each Party will pay its own expenses.

11.12.3. **Rulings**. All arbitration proceedings must be completed within 180 days of the notice of commencement of arbitration proceedings. The Parties hereby agree that, subject to the provisions of this Section 11.12.3, the arbitrator(s) has authority to issue rulings and orders regarding all procedural and evidentiary matters that the arbitrator(s) deem reasonable and necessary with or without petition therefore by the Parties as well as the final ruling and judgment. Rulings will be issued by written order summarizing the arbitration proceedings no more than 30 days after the final submissions of the Parties. All rulings by the arbitrator(s) will be final and non-appealable to any court except in circumstances where such rulings do not comply with the terms of Section 11.12.

11.12.4. **Enforcement of Rulings by Courts of Competent Jurisdiction**. Any ruling issued by the arbitrator(s) pursuant to Section 11.12 may be enforced, to the extent that such ruling complies with the provisions of Section 11.12, in any court having jurisdiction over any of the Parties or any of their respective assets.

11.12.5. **Confidentiality**. All activities undertaken by the arbitrator(s) or the Parties pursuant to this Section 11.12 will be conducted subject to obligations of confidentiality no less restrictive than those set forth in Article 7. Further, the Parties acknowledge and agree that their respective conduct during the course of the arbitration and their respective statements and all information exchanged in connection with the arbitration is Confidential Information under this Agreement and subject to the provisions of Article 7.

11.12.6. **Unauthorized Disclosure of Confidential Information to Third Parties**. Notwithstanding any provision of this Agreement to the contrary (i) the provisions of this Section 11.12 will not apply to Allogene's disclosure of Cellectis Confidential Information to any Third Party in violation of Article 7 and (ii) Cellectis reserves its rights under Section 11.10 to immediately initiate litigation seeking any remedy at law or in equity, including the issuance of a preliminary, temporary or permanent injunction, to preserve or enforce its rights under Article 7 with respect to any such unauthorized disclosure.

11.13. **Governing Law**. This Agreement, and all claims arising under or in connection therewith, will be governed by and interpreted in accordance with the substantive laws of the State of New York, without regard to conflict of law principles thereof.

11.14. **Consent to Jurisdiction**. Each Party to this Agreement, by its execution hereof, (a) hereby irrevocably submits to the exclusive jurisdiction of the courts of England and Wales for the purpose of any and all actions, suits or proceedings arising in whole or in part out of, related to, based upon or in connection with this Agreement or the subject matter hereof, (b) hereby waives to the extent not prohibited by Applicable Law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such action brought in one of the above-named courts should be dismissed on grounds of forum non conveniens, should be transferred to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court, and (c) hereby agrees not to commence any such action other than before one of the above-named courts nor to make any motion or take any other action seeking or intending to cause the transfer or removal of any such action to any court other than one of the above-named courts whether on the grounds of inconvenient forum or otherwise.

11.15. **Entire Agreement**. This Agreement, including its Exhibits and Schedules, and the letter regarding termination of the Research Collaboration and License Agreement, dated 7, 2019, constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof.

11.16. **Independent Contractors**. Both Parties are independent contractors under this Agreement. Nothing herein contained will be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party will have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

11.17. **Counterparts**. This Agreement may be executed in two counterparts, each of which will be an original and both of which will constitute together the same document. Counterparts may be signed and delivered by facsimile or PDF file, each of which will be binding when received by the applicable Party.

11.18. **No Third Party Rights or Obligations**. No provision of this Agreement will be deemed or construed in any way to result in the creation of any rights or obligation in any Person not a Party to this Agreement. However, Allogene may decide, in its sole discretion, to use one or more of its Affiliates to perform its obligations and duties hereunder, provided that Allogene will remain liable hereunder for the performance by any such Affiliates of any such obligations.

[The remainder of this page has been intentionally left blank. The signature page follows.]

IN WITNESS WHEREOF, duly authorized representatives of the Parties have duly executed this Agreement to be effective as of the Effective Date.

ALLOGENE THERAPEUTICS, INC.		CELLECTIS SA	
By:	/s/ David Chang, M.D., Ph.D.	By:	/s/ André Choulika
Name:	David Chang, M.D., Ph.D.	Name:	André Choulika
Title:	Chief Executive Officer	Title:	Chief Executive Officer

Schedule 1.13

Allogene Targets

[***]

Schedule 1.32
Cellectis Patent Rights

[***]

Schedule 1.34
Cellectis Performance Targets

[***]

Schedule 1.86

Other Cellectis Targets

[***]

Schedule 9.23

[***] Patent Rights

[***]

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 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)) 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) 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

   (c) 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 7, 2019

/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 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)) 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) 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

   (c) 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 7, 2019

/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, 2019 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 7, 2019

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

Date: May 7, 2019

/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.