

**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 September 30, 2018

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38693

Allogene Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

**210 East Grand Avenue
South San Francisco, California**

(Address of principal executive offices)

82-3562771

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

94080

(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

As of November 15, 2018, the registrant had 121,482,671 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)

	<u>September 30, 2018</u>	<u>December 31, 2017</u>
		(1)
Assets		
Current assets:		
Cash and cash equivalents	\$ 83,141	\$ —
Short-term investments	161,080	—
Prepaid expenses and other current assets	3,132	—
Total current assets	247,353	—
Long-term investments	154,045	—
Operating lease right-of-use asset	24,996	—
Property and equipment, net	4,693	—
Intangible assets, net	904	—
Restricted cash	937	—
Other long-term assets	2,307	—
Total assets	<u>\$ 435,235</u>	<u>\$ —</u>
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 3,083	\$ —
Accrued and other current liabilities	16,779	2
Convertible notes payable	139,615	—
Total current liabilities	159,477	2
Lease liability, noncurrent	25,661	—
Other long-term liabilities	7,488	—
Total liabilities	192,626	2
Commitments and Contingencies (Note 7 and 8)		
Convertible preferred stock, \$0.001 par value; 11,743,987 and 1,000,000 shares authorized as of September 30, 2018 and December 31, 2017, respectively; 11,743,987 shares and no shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively; aggregate liquidation preference of \$411.8 million as of September 30, 2018	411,052	—
Stockholders' deficit:		
Common stock, \$0.001 par value: 101,000,000 and 47,250,000 shares authorized as of September 30, 2018 and December 31, 2017, respectively; 31,270,573 and 26,249,993 shares issued and outstanding as of September 30, 2018 and December 31, 2017, respectively	31	26
Notes receivable from common stockholders	—	(5)
Additional paid-in capital	12,693	—
Accumulated deficit	(181,019)	(23)
Accumulated other comprehensive loss	(148)	—
Total stockholders' deficit	(168,443)	(2)
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 435,235</u>	<u>\$ —</u>

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

(1) The balance sheet as of December 31, 2017 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 data)

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Operating expenses:		
Research and development	\$ 10,870	\$ 133,356
General and administrative	11,317	26,440
Total operating expenses	<u>22,187</u>	<u>159,796</u>
Loss from operations	(22,187)	(159,796)
Other income (expense), net:		
Change in fair value of convertible note payable	(19,415)	(19,415)
Interest expense	(3,358)	(3,358)
Interest and other income, net	1,463	1,573
Total other income (expense), net	<u>(21,310)</u>	<u>(21,200)</u>
Net loss	(43,497)	(180,996)
Other comprehensive loss:		
Net change in available-for-sale investments	(148)	(148)
Net comprehensive loss	<u>\$ (43,645)</u>	<u>\$ (181,144)</u>
Net loss per share, basic and diluted	<u>\$ (10.71)</u>	<u>\$ (16.38)</u>
Weighted-average number of shares used in computing net loss per share, basic and diluted	<u>4,060,419</u>	<u>11,048,451</u>

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

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

	Nine Months Ended September 30, 2018
Cash flows from operating activities:	
Net loss	\$ (180,996)
Adjustments to reconcile net loss to net cash used in operating activities:	
Acquired in-process research and development	109,436
Stock-based compensation	12,695
Amortization of other intangible assets acquired	302
Depreciation and amortization	651
Net amortization/accretion on investment securities	125
Non-cash rent expense	664
Change in fair value of convertible notes payable	19,415
Debt issuance costs on convertible notes payable	3,358
Changes in operating assets and liabilities:	
Prepaid expenses and other current assets	(3,132)
Other long-term assets	(1,468)
Accounts payable	3,083
Accrued and other current liabilities	12,695
Net cash used in operating activities	(23,172)
Cash flows from investing activities:	
Purchases of property and equipment	(1,913)
Purchase of investments	(315,399)
Cash paid for acquisition of assets	(2,098)
Net cash used in investing activities	(319,410)
Cash flows from financing activities:	
Proceeds from issuance of convertible preferred stock, net of issuance costs	299,282
Proceeds from issuance of convertible notes, net of issuance costs	116,842
Proceeds from issuance of common stock and upon exercise of stock options	11,375
Payments of deferred offering costs	(839)
Net cash provided by financing activities	426,660
Net increase in cash, cash equivalents and restricted cash	\$ 84,078
Cash, cash equivalents and restricted cash — beginning of period	—
Cash, cash equivalents and restricted cash — end of period	\$ 84,078
Non-cash investing and financing activities:	
Series A-1 convertible preferred stock issued in asset acquisition	\$ 111,770
Right-of-use asset obtained in exchange for lease liability	\$ 25,322
Deferred offering costs included in accounts payable and accrued and other current liabilities	\$ 1,388
Property and equipment purchase in accounts payable and accrued liabilities	\$ 204

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

ALLOGENE THERAPEUTICS, INC.
Notes to 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.

For the period from November 30, 2017 (inception) to December 31, 2017, the Company incurred \$2,000 in start-up costs to establish the Company. Principal operations commenced in April 2018 when Allogene acquired certain assets from Pfizer Inc. (Pfizer) (see Note 6) and completed a Series A and A-1 preferred stock financing (see Note 10).

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 \$3.5 million payable by the Company. At the closing of the IPO, 11,743,987 shares of outstanding convertible preferred stock were automatically converted into 61,655,922 shares of common stock and the 2018 Notes (see Note 9) were automatically converted into 7,856,176 shares of common stock. Following the IPO, there were no shares of preferred stock outstanding. As of September 30, 2018, the Company had incurred \$2.2 million of deferred offering costs, which will be offset against the net proceeds received from the sale of common stock.

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 \$398.3 million as of September 30, 2018. Since inception through September 30, 2018, the Company has incurred cumulative net losses of \$181.0 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 such additional capital through the issuance of equity securities, debt financings or other sources in order to further implement its business plan. However, if such financing is not available at adequate levels, the Company will need to reevaluate its operating plan and may be required to delay the development of its product candidates. The Company expects that its cash and cash equivalents and investments will be sufficient to fund its operations for a period of at least one year from the date the 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 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 consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP) for interim financial information and pursuant to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (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 September 30, 2018, the condensed statements of operations and comprehensive loss for the three and nine months ended September 30, 2018, the condensed statement of cash flows for the nine months ended September 30, 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 and nine months ended September 30, 2018 are not necessarily indicative of the results to be expected for the year ending December 31, 2018 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 included in the prospectus dated October 10, 2018 that forms a part of the Company's Registration Statements on Form S-1 (File Nos. 333-227333 and 333-227774), as filed with the SEC pursuant to Rule 424 promulgated under the Securities Act of 1933, as amended, on October 11, 2018.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (U.S. 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.

Cash, Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments purchased with original maturities of three months or less from the purchase date to be cash equivalents. Cash equivalents consist primarily of amounts invested in money market accounts.

The Company has issued a letter of credit under a lease agreement which has been collateralized by restricted cash. This cash is classified as long-term restricted cash on the accompanying condensed balance sheet based on the term of the underlying lease.

Investments

Investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. Management determines the appropriate classification of its investments in debt securities at the time of purchase. Investments with original maturities beyond three months at the date of purchase and which mature at, or less than twelve months from the balance sheet date are classified as current.

Unrealized gains and losses are excluded from earnings and are reported as a component of comprehensive loss. The Company periodically evaluates whether declines in fair values of its available-for-sale securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the available-for-sale security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any available-for-sale securities before recovery of its amortized cost basis. Realized gains and losses and declines in fair value judged to be other than temporary, if any, on available-for-sale securities are included in interest and other income, net. The cost of investments sold is based on the specific-identification method. Interest income on investments is included in interest and other income, net.

Fair Value Measurement

Assets and liabilities recorded at fair value on a recurring basis in the balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

Level 1—Observable inputs such as unadjusted, quoted prices in active markets for identical assets or liabilities at the measurement date.

Level 2—Inputs (other than quoted prices included in Level 1) are either directly or indirectly observable for the asset or liability. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

Level 3— Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Deferred Offering Costs

Offering costs, including legal, accounting, and filing fees related to the IPO, were deferred and were offset against the offering proceeds upon the completion of the IPO. As of September 30, 2018, \$2.2 million of deferred offering costs have been capitalized, which is included in other long-term assets in the accompanying condensed balance sheet. There were no deferred offering costs recorded as of December 31, 2017.

Leases

The Company early adopted Accounting Standards Update (ASU) No. 2016-02, Leases as of January 1, 2018 in accordance with ASC 250, *Accounting Changes and Error Corrections*. For its long-term operating lease, the Company recognized a right-of-use asset and a lease liability on its balance sheet. The lease liability is determined as the present value of future lease payments using an estimated rate of interest that the Company would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The right-of-use asset is based on the liability adjusted for any prepaid or deferred rent. The lease term at the commencement date is determined by considering whether renewal options and termination options are reasonably assured of exercise.

Rent expense for the operating lease is recognized on a straight-line basis over the lease term and is included in operating expenses on the statements of operations and comprehensive loss. Variable lease payments include lease operating expenses.

The Company elected to exclude from its balance sheets recognition of leases having a term of 12 months or less (short-term leases) and elected to not separate lease components and nonlease components for its long-term real estate leases.

Accrued Research and Development Costs

The Company records accrued liabilities for estimated costs of research and development activities conducted by collaboration partners and third-party service providers, which include the conduct of preclinical studies and clinical trials, and contract manufacturing activities. The Company records the estimated costs of research and development activities based upon the estimated amount of services provided but not yet invoiced, and includes these costs in accrued and other current liabilities on its condensed balance sheets and within research and development expenses on the statements of operations.

The Company accrues for these costs based on factors such as estimates of the work completed and in accordance with agreements established with its collaboration partners and third-party service providers. The Company makes significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, the Company adjusts its accrued liabilities. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses for the nine months ended September 30, 2018 primarily consist of acquired intangible assets as research and development costs pursuant to the Asset Contribution Agreement with Pfizer (see Note 7) as, at the time of acquisition of the asset, the technology was under development; was not approved by the U.S. Food and Drug Administration or other regulatory agencies for marketing; had not reached technical feasibility; or otherwise had no foreseeable alternative future use. For the nine months ended September 30, 2018, the Company recognized expense of \$109.4 million related to the acquired intangible in-process research and development.

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

Recently Adopted Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update No. 2016-09, *Stock Compensation—Improvements to Employee Share-Based Payment Accounting* (ASU 2016-09). ASU 2016-09 was issued to simplify accounting guidance by identifying, evaluating, and improving areas for which cost and complexity can be reduced while maintaining or improving the usefulness of the information provided to users of financial statements. The areas affected by ASU 2016-09 include accounting for income taxes, classification of excess tax benefits on the statement of cash flows, minimum statutory tax withholding requirements, and classification of employee taxes paid on the statement of cash flows when an employer withholds shares for tax-withholding purposes. In addition, under this guidance, an entity can make an accounting policy election to either estimate the number of awards that are expected to vest or account for forfeitures when they occur. The Company adopted this guidance beginning with the period from November 30, 2017 (inception) to December 31, 2017, and elected a policy to account for forfeitures as they occur.

In January 2017, the FASB issued Accounting Standards Update, *Business Combinations (Topic 805): Clarifying the Definition of a Business* (ASU 2017-01). ASU 2017-01 clarifies the framework for determining whether an integrated set of assets and activities meets the definition of a business. The revised framework establishes a screen for determining whether an integrated set of assets and activities is a business and narrows the definition of a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated. This new accounting guidance is effective for public or private companies for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The new accounting guidance should be applied prospectively on or after the effective date. The Company adopted this guidance on January 1, 2018.

In June 2018, the FASB issued Accounting Standards Update No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting* (ASU 2018-07). ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. Some of the areas of simplification apply only to nonpublic entities. For all entities, the amendments are effective for annual periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted for any entity in any interim or annual period for which financial statements haven't been issued or made available for issuance, but not before an entity adopts ASC 606. The Company early adopted this guidance on January 1, 2018.

In November 2016, the FASB issued Accounting Standards Update No. 2016-18, *Statement of Cash Flows: Restricted Cash*. This ASU requires changes in restricted cash during the period to be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. If cash, cash equivalents and restricted cash are presented in more than one line item on the balance sheet, the new guidance requires a reconciliation of the total in the statement of cash flows to the related captions in the balance sheet. This guidance is effective for annual and interim periods of public entities beginning after December 15, 2017, with early adoption permitted. The amendments in this ASU should be applied retrospectively to all periods presented. The Company adopted this guidance on January 1, 2018. The adoption of this ASU increased our beginning and ending cash balances within the condensed statements of cash flows. The adoption had no other material impacts to the condensed statements of cash flows and had no impact on the results of operations or financial position.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases* (ASU 2016-02), which provides revised accounting requirements for both lessees and lessors. Lessees will recognize a right-of-use asset and a lease liability for virtually all leases (other than short-term leases upon election). The liability is recognized at the present value of future lease payments. The asset is recognized based on the liability. For statement of operations purposes, ASU 2016-02 requires leases to be classified as either operating or finance. Operating leases will result in straight-line expense while finance leases will result in a front-loaded expense pattern. ASU 2016-02 is effective for public companies for fiscal years beginning after December 15, 2018. For all other entities, this standard is effective for annual reporting periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020. Early adoption is permitted. The standard requires a modified-retrospective transition method and provides for certain practical expedients.

The Company early adopted Accounting Standards Update (ASU) No. 2016-02, *Leases* as of January 1, 2018 in accordance with ASC 250, *Accounting Changes and Error Corrections*. The Company elected not to apply any of the transitional practical expedients. As of September 30, 2018, the Company has one long-term operating lease that commenced on August 1, 2018. Consequently, the adoption of the standard did not have any impact on prior periods.

Recent Accounting Pronouncements Not Yet Adopted

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 does not expect the adoption of this standard to have a material effect on the condensed financial statements.

In August 2018, the FASB issued Accounting Standards Update No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. This standard is effective for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company does not expect the adoption of this standard to have a material effect on the condensed financial statements.

3. Fair Value Measurements

The Company measures and reports its cash equivalents, restricted cash, investments and convertible notes payable 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.

Level 3 liabilities consist of the convertible note payable. The determination of the fair value of the convertible note payable and the change in the fair value of the convertible notes payable is discussed in Note 9.

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 September 30, 2018 are presented in the following tables:

	September 30, 2018			Fair Value
	Level 1	Level 2	Level 3	
(in thousands)				
Financial Assets:				
Money market funds	\$ 6,524	\$ —	\$ —	\$ 6,524
Corporate bonds	—	163,319	—	163,319
U.S. treasury securities	224,947	—	—	224,947
Total financial assets	<u>\$ 231,471</u>	<u>\$ 163,319</u>	<u>\$ —</u>	<u>\$ 394,790</u>
Financial Liabilities:				
Convertible notes payable	\$ —	\$ —	\$ 139,615	\$ 139,615
Total financial liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 139,615</u>	<u>\$ 139,615</u>

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 September 30, 2018 are presented in the following table:

	September 30, 2018			Fair Value
	Amortized Cost	Unrealized Gains	Unrealized Losses	
(in thousands)				
Money market funds	\$ 6,524	\$ —	\$ —	\$ 6,524
Corporate bonds	163,413	18	(112)	163,319
U.S. treasury securities	225,001	—	(54)	224,947
Total cash equivalents, restricted cash and investments	<u>\$ 394,938</u>	<u>\$ 18</u>	<u>\$ (166)</u>	<u>\$ 394,790</u>
Classified as:				
Cash equivalents				\$ 78,728
Restricted cash				937
Short-term investments				161,080
Long-term investments				154,045
Total cash equivalents, restricted cash and investments				<u>\$ 394,790</u>

As of September 30, 2018, the remaining contractual maturities of available-for-sale securities were less than two years. There have been no significant realized losses on available-for-sale securities for the period presented. Available-for-sale debt securities that were in a continuous loss position but were not deemed to be other than temporarily impaired were immaterial as of September 30, 2018.

5. Balance Sheet Components

Intangible Assets, Net

	September 30, 2018		
	Cost	Accumulated Amortization	Carrying Value
(in thousands)			
Assembled workforce	\$ 1,206	\$ (302)	\$ 904

As of September 30, 2018, the weighted-average remaining amortization period of the assembled workforce was 1.51 years. Amortization expense related to the assembled workforce was \$0.2 million and \$0.3 million for the three and nine months ended September 30, 2018, respectively.

Accrued Liabilities

Accrued liabilities consist of the following:

	September 30,	December 31,
	2018	2017
(In thousands)		
Accrued research and development expenses	\$ 6,584	\$ —
Unvested shares liabilities	3,883	—
Accrued compensation and related benefits	1,728	—
Accrued offering costs	579	—
Accrued professional and consulting services	2,066	—
Other	1,939	2
Total accrued and other current liabilities	\$ 16,779	\$ 2

6. Asset Acquisition

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 described in Note 7, and intellectual property for the development and administration of chimeric antigen receptor (CAR) T cells for the treatment of cancer.

As consideration for the purchased assets, the Company issued Pfizer 3,187,772 shares of its Series A-1 convertible preferred stock with an estimated fair value of \$111.8 million or \$35.06 per share. The Company also incurred \$2.1 million of direct expenses related to the asset acquisition, bringing the total consideration to \$113.9 million. The fair value of the Series A-1 convertible preferred stock was established using the price per share paid by third-party investors in the concurrent closing of the Series A and A-1 convertible preferred stock financing of \$35.06 per share as well as the price per share paid by Pfizer to purchase additional shares of Series A-1 convertible preferred stock at \$35.06 per share at the same time and at the same price per share as the rest of Series A and A-1 shares sold in such financing (see Note 10 for additional details). The Series A-1 convertible preferred shares issued to Pfizer had the same rights, preferences and privileges as the Series A convertible preferred shares issued to the third-party investors.

The Company accounted for the transaction as an asset acquisition as substantially all of the estimated fair value of the gross assets acquired was concentrated in a single identified asset, anti-CD19 CAR T cell therapy, thus satisfying the requirements of the screen test in ASU 2017-01. The assets acquired in the transaction were measured based on the fair value of the Series A-1 convertible preferred stock issued to Pfizer and direct transaction costs of \$2.1 million, as the fair value of the equity given was more readily determinable than the fair value of the assets received. The following table summarizes the fair value of assets acquired (in thousands):

Property and equipment	\$	3,258
In-process research and development (IPR&D):		
Anti-CD19 CAR T cell therapy		103,936
Anti-BCMA CAR T cell therapy		5,500
Assembled workforce		1,206
Total assets acquired	\$	<u>113,900</u>

The estimated fair values of anti-CD19 CAR T cell therapy and anti-BCMA CAR T cell therapy were determined using a risk-adjusted discounted cash flow approach, which used the present value of the direct cash flows expected to be generated by anti-CD19 CAR T cell therapy and anti-BCMA CAR T cell therapy during their estimated economic lives, net of returns on contributory assets such as working capital, property and equipment, and the assembled workforce. The discount rate of 16.5% was based on rates of return available from alternative investments of similar type and quality as of the valuation date. The remaining IPR&D targets were determined to be more conceptual in nature with nominal value being attributed to them. The estimate of the fair value of the assembled workforce was determined using a replacement cost approach, based off the estimated cost of recruiting and training an equivalent workforce as of the acquisition date.

The amount allocated to intangible IPR&D assets was charged to research and development expenses as these assets had no alternative future use at the time of the acquisition transaction. The remaining intangible asset relates to the assembled workforce which was capitalized and is being amortized over its estimated economic life of two years to research and development expenses.

In addition, under the terms of the Pfizer Agreement, the Company is also required to make milestone payments to Pfizer of \$30.0 million or \$60.0 million per target (depending on the target, and up to \$840.0 million in the aggregate for all targets) upon successful completion of certain regulatory and sales milestones for certain targets covered by the Pfizer Agreement. These contingent payments are not part of the consideration for the purchased assets.

As part of the asset acquisition, the Company also assumed licensing agreements Pfizer had entered into with two third-party entities holding certain intellectual property. Both agreements cover use of the intellectual property held by the parties and certain research collaboration activities. See Note 7 for additional details on these agreements.

Under the Pfizer Agreement, the Company is required to use commercially reasonable efforts to develop and seek regulatory approval in and for the United States and the European Union for certain products covered by the Pfizer Agreement and to commercialize each product covered by the Pfizer Agreement in the applicable royalty territory in which regulatory approval for such product has been obtained.

7. License Agreements

Asset Contribution Agreement with Pfizer

In connection with the Pfizer Agreement (see Note 6), 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.

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 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 (see Note 6), Pfizer assigned to the Company a Research Collaboration and License Agreement (the Cellectis Agreement) with Cellectis S.A. (Cellectis). Pursuant to the Cellectis Agreement, the Company has an exclusive, worldwide, royalty-bearing, sublicensable license, on a target-by-target basis, under certain of Cellectis's intellectual property to make, use, sell, import, and otherwise commercialize products directed at certain targets for the treatment of cancer.

The 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. Pursuant to the terms of the Cellectis Agreement, the research collaboration ended in June 2018. Cellectis has a non-exclusive, worldwide, royalty-free, perpetual and irrevocable license, with sublicensing rights under certain conditions, under certain of the Company's intellectual property to conduct research, and to make, use, sell, import and otherwise commercialize products directed at Cellectis-selected targets.

The Cellectis Agreement requires Allogene to make payments of up to \$185.0 million per product that is directed against a Company-selected target, with aggregate maximum potential pre-clinical, clinical and commercial milestone payments totaling up to \$2.8 billion across all potential targets. 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, or are covered by, certain of Cellectis's intellectual property at rates in the high single-digit percentages.

Unless earlier terminated in accordance with the agreement, the Cellectis Agreement will expire on a product-by-product and country-by-country basis, on 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 will the term extend, with respect to a particular licensed product, past the twentieth anniversary of the first commercial sale for such product.

All costs the Company incurred in connection with this agreement were recognized as research and development expenses. For the nine months ended September 30, 2018, \$0.4 million of costs have been incurred associated with research services performed by Cellectis. For the three months ended September 30, 2018, no cost has been incurred associated with research services performed by Cellectis. As of September 30, 2018, no 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 (see Note 6), 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, the Company is responsible for 60% of the development costs and Servier is responsible for the remaining 40% of the development costs under the 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 (\$81.9 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 and nine months ended September 30, 2018, the Company recorded \$4.8 million and \$7.5 million of the costs incurred under the cost-sharing terms of the Servier Agreement as research and development expenses. As of September 30, 2018, \$4.6 million was recorded in the accrued and other current liabilities in the accompanying condensed balance sheet.

8. Commitments and Contingencies

Leases

In August 2018, the Company entered into an operating lease agreement for new office and laboratory space which consists of approximately 68,000 square feet located in South San Francisco, California. The lease term is 127 months beginning August 2018 through February 2029 with an option to extend the term for another seven years which is not reasonably assured of exercise. The Company has the right to make tenant improvements, including the addition of laboratory space, with a lease incentive allowance of \$5.1 million. The rent payments begin 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 \$0.9 million.

In connection with the lease, the Company recognized an operating lease right-of-use asset of \$25.0 million as of September 30, 2018 and an aggregate lease liability of \$25.7 million in its condensed balance sheet.

The remaining lease term is 10.4 years, and the discount rate is 8.0%.

The undiscounted future lease payments under the lease liability as of September 30, 2018 were as follows:

Year ending December 31:	(in thousands)
2018 (remaining three months)	\$ —
2019	2,406
2020	4,245
2021	4,394
2022	4,548
2023 and thereafter	31,769
Total undiscounted lease payments	47,362
Less: Present value adjustment	(16,596)
Less: Tenant improvement allowance	(5,105)
Total	\$ 25,661

Rent expense for the operating lease was \$0.7 million for both the three and nine months ended September 30, 2018, respectively. Short-term lease expense was \$1.0 million and \$1.7 million for the three and nine months ended September 30, 2018, respectively. Variable lease payments for operating expenses were immaterial for the three and nine months ended September 30, 2018.

9. Convertible Notes Payable (2018 Notes)

In September 2018, the Company entered into a note purchase agreement pursuant to which it sold and issued an aggregate of \$120.2 million in convertible promissory notes (convertible notes payable or 2018 Notes) and received net cash proceeds of \$116.8 million.

The 2018 Notes did not accrue interest. The 2018 Notes were settled in 7,856,176 shares of common stock in connection with the closing of the Company's IPO (see Note 1) at a settlement price equal to 85% of the IPO price per share. The 2018 Notes also contained other settlement provisions if an IPO did not occur within one year of the 2018 Notes issuance date. If the Company was acquired, completed a business combination resulting in a change of control or sold all or substantially all of its assets (each, a "liquidation transaction") prior to the one-year anniversary of the issuance date of the 2018 Notes, the 2018 Notes would settle into shares of common stock at a price per share equal to 85% of the estimated fair value of the consideration per share payable to the holders of common stock in connection with such liquidation transaction. If neither the IPO nor a liquidation transaction occurred prior to the one-year anniversary of the issuance date of the 2018 Notes, the 2018 Notes would convert into shares of the Company's newly designated Series B convertible preferred stock at a settlement price per share that would be determined based on a stipulated \$900.0 million valuation of the Company and its fully diluted capitalization as of immediately prior to the conversion of the 2018 Notes. The 2018 Notes also contained additional redemption features contingent upon the occurrence of certain future events.

On issuance, the Company elected to account for the 2018 Notes at fair value with any changes in fair value being recognized through the statements of operations until the 2018 Notes settled. The fair value of the 2018 Notes was determined to be \$120.2 million on issuance and \$139.6 million as of September 30, 2018. For the three-months and nine-months ended September 30, 2018, the Company recognized \$19.4 million in the accompanying condensed statements of operations as the change in fair value of the 2018 Notes. On issuance, total debt issuance costs of \$3.4 million were expensed and recognized as interest expense in the accompanying condensed statements of operations.

Fair Value

On issuance, the fair value of the 2018 Notes was determined to be equal to \$120.2 million, which is the principal amount of the 2018 Notes.

The Company determined the fair value of the 2018 Notes as of September 30, 2018 by determining the present value of the 2018 Notes if they were to settle either upon the closing of an IPO or in shares of Series B convertible preferred stock one year after issuance (September 2019). Key valuation assumptions are as follows:

	As of September 30, 2018	
	IPO Scenario	Series B Scenario
Expected term (years)	0.03 – 0.10	1 year
Discount rate	20%	—
Weighting	95%	5%

10. Convertible Preferred Stock and Stockholders' Deficit

Convertible Preferred Stock

As discussed in Note 6, the Company issued 3,187,772 shares of its Series A-1 convertible preferred stock to Pfizer in connection with the Pfizer Agreement entered into in April 2018.

In April 2018, the Company issued 7,557,990 shares of its Series A convertible preferred stock at a price per share of \$35.06 for net cash proceeds of \$264.4 million and issued 998,225 shares of Series A-1 convertible preferred stock at a price per share of \$35.06 for net cash proceeds of \$34.9 million. Fifty percent of the aggregate purchase price of \$300.0 million was paid in April 2018. The remaining subscriptions receivable of \$150.0 million was received in July and August 2018, at the election of the Company's board of directors.

Convertible preferred stock consisted of the following:

	September 30, 2018			
	Shares Authorized	Shares Issued and Outstanding	Net Carrying Value	Aggregate Liquidation Preference
	(In thousands, except share amounts)			
Series A	7,557,990	7,557,990	\$ 264,365	\$ 265,000
Series A-1	4,185,997	4,185,997	146,687	146,770
	<u>11,743,987</u>	<u>11,743,987</u>	<u>\$ 411,052</u>	<u>\$ 411,770</u>

The Company classified the convertible preferred stock outside of stockholders' deficit because, in the event of certain "liquidation events" that are not solely within the control of the Company (including merger, acquisition, or sale of all or substantially all of the assets), the shares would become redeemable at the option of the holders. The Company did not adjust the carrying values of the convertible preferred stock to the deemed liquidation values of such shares since a liquidation event was not probable at the reporting date.

On the completion of the IPO (see Note 1), all outstanding shares of convertible preferred stock were automatically converted into 61,655,922 shares of common stock.

Common Stock

Pursuant to the Amended and Restated Certificate of Incorporation filed on April 5, 2018, as amended, the Company was authorized to issue a total of 101,000,000 shares of common stock, of which 31,270,573 shares were issued and outstanding at September 30, 2018.

In connection with the issuance of the Company's Series A convertible preferred stock in April 2018, the Company's founders agreed to modify their common shares outstanding to include vesting provisions that require continued service to the Company in order to vest in those shares. As such, the 26,249,993 modified shares of common stock became compensatory upon such modification. The total compensation cost resulting from the modification is approximately \$59.5 million and is being recognized over the four-year vesting term. For the three and nine months ended September 30, 2018, the Company recognized \$3.4 million and \$11.4 million of this amount in general and administrative expense in the accompanying condensed statements of operations.

Common stockholders are entitled to dividends if and when declared by the Company's board of directors subject to the prior rights of the preferred stockholders. As of September 30, 2018, no dividends on common stock had been declared by the Company's board of directors.

11. 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. Under the terms of the 2018 Plan, options may be granted at an exercise price not less than fair market value. 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.

As of September 30, 2018, there were 1,112,753 shares reserved by the Company under the 2018 Plan for the future issuance of equity awards.

The following summarizes option activity under the 2018 Plan:

	<u>Number of Options</u>	<u>Weighted- Average Exercise Price</u>	<u>Weighted- Average Remaining Contract Term (In years)</u>
Balance, December 31, 2017	—	\$ —	
Options granted	11,156,250	\$ 3.23	
Options exercised	(5,020,580)	\$ 2.26	
Options forfeited	(59,851)	\$ 2.26	
Balance, September 30, 2018	<u>6,075,819</u>	\$ 4.04	<u>9.81</u>
Exercisable, September 30, 2018	<u>2,657,550</u>	\$ 3.94	<u>9.81</u>
Vested and expected to vest, September 30, 2018	<u>6,075,819</u>	\$ 4.04	<u>9.81</u>

Total stock-based compensation related to stock options and modification of the founders' common stock (see Note 10) was as follows:

	<u>Three Months Ended September 30, 2018</u>	<u>Nine Months Ended September 30, 2018</u>
	<u>(In thousands)</u>	
Research and development	\$ 427	\$ 442
General and administrative	4,212	12,253
Total stock-based compensation	<u>\$ 4,639</u>	<u>\$ 12,695</u>

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 September 30, 2018, there was \$3.9 million recorded in accrued and other liabilities and \$7.5 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.

12. Related Party Transactions

As of September 30, 2018, Pfizer held 4,185,997 shares of Series A-1 convertible preferred stock and had appointed two members 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 and nine months ended September 30, 2018, the costs incurred under the Pfizer TSA were \$3.8 million and \$7.4 million, respectively. The costs for the three and nine months ended September 30, 2018, were recorded in general and administrative expense in the amounts of \$1.9 million and \$3.7 million, respectively, and in research and development expense in the amounts \$1.9 million and \$3.7 million, respectively.

The Company also purchased certain lab supplies from Pfizer in connection with its research and development activities. For the three and nine months ended September 30, 2018, the total lab supplies and services purchased from Pfizer was \$2.8 million and \$6.1 million, respectively, which were recorded as research and development expense.

As of September 30, 2018, the Company had an amount payable to Pfizer of \$4.4 million, which was recorded in the accrued and other current liabilities on the accompanying condensed balance sheets.

Consulting Agreements

In June 2018, the Company entered into a services agreement with 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. Additionally, in June 2018 the Company entered into a consulting services agreement with a firm affiliated with a beneficial owner of more than 5% of the Company's capital stock. The costs incurred for services provided under these agreements were \$0.3 million and \$0.7 million for the three and nine months ended September 30, 2018, respectively, and were included in general and administrative expenses.

In August 2018, the Company entered into a consulting agreement with Bellco Capital LLC (Bellco). The Company's executive chairman, Arie Belldregun, 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. Belldregun 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 \$26,250 per month in arrears commencing June 2018 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 \$0.1 million and \$0.1 million for the three and nine months ended September 30, 2018 and were included in general and administrative expenses.

13. Income Taxes

In December 2017, the Tax Cuts and Jobs Act (Tax Act) was signed into law. The Tax Act, among other changes, lowers the Company's federal tax rate from 34% to 21%. Based on provisions of the Tax Act, the Company remeasured its deferred tax assets and liabilities as of December 31, 2017 to reflect the lower statutory tax rate. However, since the Company established a valuation allowance to offset its deferred tax assets, there was no impact to the effective tax rate, as any changes to deferred taxes would be offset by the valuation allowance. The deferred tax remeasurement is provisional and is subject to revision as the Company completes its analysis of the Tax Act, collects and prepares necessary data and interprets any additional guidance issued by standard-setting bodies. The Company currently anticipates finalizing and recording any resulting adjustments related to the tax effects of the Tax Act in 2018.

14. 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 September 30, 2018	Nine Months Ended September 30, 2018
	(In thousands)	
Convertible preferred stock (on an as-converted basis)	61,655,922	61,655,922
Convertible notes payable (on an as-converted basis)	7,856,176	7,856,176
Stock options to purchase common stock	6,075,819	6,075,819
Founder shares of common stock subject to future vesting	21,201,908	21,201,908
Early exercised stock options subject to future vesting	5,020,575	5,020,575
Total	<u>101,810,400</u>	<u>101,810,400</u>

15. Subsequent Event

In October 2018, the Company entered into an operating lease agreement for office and laboratory space in South San Francisco, California near the Company headquarters. The lease has a term of ten years and four months commencing on November 1, 2018. Upon certain conditions, the Company has an option to extend the lease for an additional seven years. The aggregate lease payment amounts over the lease term are approximately \$10.8 million. This lease agreement provides for aggregate tenant improvement allowances of \$0.8 million, which are amortized as a reduction to rent expense on a straight-line basis over the lease term. In connection with the lease, the Company will maintain a letter of credit for the benefit of the landlord in the amount of \$0.2 million.

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 our audited financial statements and notes thereto included in our final prospectus dated October 10, 2018 (Prospectus), as filed with the Securities and Exchange Commission pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on October 11, 2018. 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.

In collaboration with Servier, we are developing UCART19, a chimeric antigen receptor (CAR) T cell product candidate targeting CD19. UCART19 is being studied in two Phase 1 clinical trials 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). We plan to submit an investigational new drug application (IND) in the first half of 2019 for our second allogeneic anti-CD19 CAR T cell product candidate, ALLO-501, for the treatment of non-Hodgkin lymphoma (NHL). ALLO-501 is identical in molecular design to UCART19, but is produced using a modified manufacturing process, optimized by us. In addition, 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. For example, we plan to submit an IND in 2019 for ALLO-715, an allogeneic CAR T cell product candidate targeting B-cell maturation antigen (BCMA), for the treatment of multiple myeloma.

Servier is the sponsor of the UCART19 clinical trials and is also responsible for manufacturing UCART19. Servier is currently experiencing manufacturing challenges, which will delay enrollment in the UCART19 clinical trials. We are working together with Servier to resolve the manufacturing challenges. We will be the sponsor of the clinical trials for ALLO-501 and ALLO-715, and we will also be responsible for manufacturing ALLO-501 and ALLO-715. We believe the UCART19 manufacturing challenges have no effect on our manufacturing or program timelines for ALLO-501 and ALLO-715. We will also manage all other aspects of the supply of ALLO-501 and ALLO-715, including planning, contract manufacturing oversight, disposition and distribution logistics.

Since inception, we have had significant operating losses, the vast majority of which are attributable to acquired intangible in-process research and development costs pursuant to the Asset Contribution Agreement with Pfizer Inc. (Pfizer) described below. Our net loss was \$43.5 million and \$181.0 million for the three and nine months ended September 30, 2018, respectively. As of September 30, 2018, we had an accumulated deficit of \$181.0 million. As of September 30, 2018, we had \$398.3 million in cash and cash equivalents and investments. In October 2018, we completed an initial public offering (IPO) of our common stock. As a result of the IPO, we received approximately \$343.0 million in net proceeds. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. 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

Asset Contribution Agreement with Pfizer

In April 2018, we entered into an Asset Contribution Agreement (Pfizer Agreement) with Pfizer pursuant to which we acquired certain assets and assumed certain liabilities from Pfizer, including the Collectis Agreement and the Servier Agreement described below and other intellectual property for the development and administration of CAR T cells for the treatment of cancer. See Notes 6 and 7 to our condensed financial statements included elsewhere in this report for further description of the Pfizer Agreement.

Research Collaboration and License Agreement with Collectis

In June 2014, Pfizer entered into a Research Collaboration and License Agreement (Collectis Agreement) with Collectis S.A. (Collectis). In April 2018, Pfizer assigned the agreement to us pursuant to the Pfizer Agreement. See Note 7 to our condensed financial statements included elsewhere in this report for further description of the Collectis 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 7 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 will continue providing the services for a period of time ranging from one to 12 months, depending on the service, which we refer to as the Service Period, with the exception of the services relating to the facilities, which Pfizer shall provide for 18 months. The services and employees for each service may be amended from time to time by the parties. Under the TSA, we estimate we will pay Pfizer an aggregate of \$10.4 million in 2018 and \$3.8 million in 2019.

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 for 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 for the three and nine months ended September 30, 2018 primarily consist of acquired in-process research and development recognized as a non-cash expense related to the Pfizer Agreement. Research and development expenses consist primarily of costs incurred for the development of our most advanced product candidate, UCART19, which include:

- expenses incurred under agreements with our collaboration partners and third-party contract organizations, investigative clinical trial sites that conduct research and development activities on our behalf, and consultants;
- costs related to production of clinical materials, including fees paid 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.

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. 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;
- 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 number of doses 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. Due to the early stage nature of our programs, we do not track costs on a project by project basis. As our programs become more advanced, we intend to track the external and internal cost of each program.

General and Administrative

General and administrative expenses consist primarily of salaries and other staff-related costs, including stock-based compensation for options granted and modification of shares of common stock issued to our founders to include vesting conditions, for personnel in executive, commercial, finance, accounting, legal, investor relations, facilities, business development 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, 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.

Change in Fair Value of 2018 Notes

We elected on issuance to account for our convertible promissory notes (2018 Notes) at fair value until their settlement. In this reporting period, the change in fair value of the 2018 Notes was recognized through the statement of operations. The 2018 Notes settled on the closing of our IPO in October 2018.

Interest Expense

Interest expense consists of debt issuance costs we incurred to issue the 2018 Notes. The debt issuance costs were expensed on issuance because we elected to record the 2018 Notes at fair value.

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 September 30, 2018

The following sets forth our results of operations for the three months ended September 30, 2018 (in thousands):

	Three Months Ended September 30, 2018
Operating expenses:	
Research and development	\$ 10,870
General and administrative	11,317
Total operating expenses	22,187
Loss from operations	(22,187)
Other income (expense), net:	
Change in fair value of convertible note payable	(19,415)
Interest expense	(3,358)
Interest and other income, net	1,463
Total other income (expense), net	(21,310)
Net loss	\$ (43,497)

Research and Development Expenses

Research and development expenses were \$10.9 million for the three months ended September 30, 2018. Research and development expenses consisted primarily of \$4.2 million in external costs to our research and development partners related to product candidate development activities and manufacturing support for UCART19 clinical trials, \$3.9 million for personnel-related costs, and \$1.9 million for expenses incurred under the TSA.

General and Administrative Expenses

General and administrative expenses were \$11.3 million for the three months ended September 30, 2018. General and administrative expenses consisted primarily of \$4.2 million in stock-based compensation resulting from the modification of our founders' shares of common stock to include vesting conditions and new stock option grants to employees, \$3.0 million for personnel-related costs, \$1.9 million for expenses incurred under the TSA, and \$1.2 million in advisory costs, including legal fees and professional consulting service fees, related to supporting the growth of the Company.

Change in Fair Value of 2018 Notes

The change in fair value of convertible notes payable of \$19.4 million for the three months ended September 30, 2018 was directly attributable to the Company's progress towards completing an IPO from the issuance date of the 2018 Notes through September 30, 2018.

Interest Expense

Interest expense of \$3.4 million for the three months ended September 30, 2018 consist of debt issuance costs that were expensed on issuance of the 2018 Notes.

Interest and Other Income, Net

Interest and other income, net was \$1.5 million for the three months ended September 30, 2018 and consist of interest earned on our cash equivalents during the period.

Nine Months Ended September 30, 2018

The following sets forth our results of operations for the nine months ended September 30, 2018 (in thousands):

	Nine Months Ended September 30, 2018
Operating expenses:	
Research and development	\$ 133,356
General and administrative	26,440
Total operating expenses	159,796
Loss from operations	(159,796)
Other income (expense), net:	
Change in fair value of convertible note payable	(19,415)
Interest expense	(3,358)
Interest and other income, net	1,573
Total other income (expense), net	(21,200)
Net loss	<u>\$ (180,996)</u>

Research and Development Expenses

Research and development expenses were \$133.4 million for the nine months ended September 30, 2018. Research and development expenses consisted primarily of a non-cash charge of \$109.4 million associated with acquired in-process research and development assets with no alternative future use purchased from Pfizer, \$12.5 million in external costs to our research and development partners related to product candidate development activities and manufacturing support for UCART19 clinical trials, \$6.3 million for personnel-related costs, and \$3.7 million for expenses incurred under the TSA.

General and Administrative Expenses

General and administrative expenses were \$26.4 million for the nine months ended September 30, 2018. General and administrative expenses consisted primarily of \$12.3 million in stock-based compensation expense resulting from the modification of our founders' shares of common stock to include vesting conditions and new stock option grants to employees, \$4.8 million in advisory costs, including legal fees and professional consulting service fees, related to supporting the growth of the Company, \$4.3 million for personnel-related costs and \$3.7 million for expenses incurred under the TSA.

Change in Fair Value of 2018 Notes

The change in fair value of convertible notes payable of \$19.4 million for the nine months ended September 30, 2018 was directly attributable to the Company's progress towards completing an IPO from the issuance date of the 2018 Notes through September 30, 2018.

Interest Expense

Interest expense of \$3.4 million for the nine months ended September 30, 2018 consist of debt issuance costs that were expensed on issuance of the 2018 Notes.

Interest and Other Income, Net

Interest and other income, net was \$1.6 million for the nine months ended September 30, 2018 and consist of interest earned on our cash equivalents during the period.

Liquidity, Capital Resources and Plan of Operations

To date, we have incurred significant net losses and negative cash flows from operations. Prior to our IPO, our operations have been financed primarily by net proceeds from the sale and issuance of our convertible preferred stock and the issuance of the 2018 Notes. As of September 30, 2018, we had \$398.3 million in cash and cash equivalents and investments and the fair value of our outstanding 2018 Notes was \$139.6 million. 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 12 months following the filing date of this report.

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, the 2018 Notes were automatically converted into 7,856,176 shares of common stock.

Debt Obligations

In September 2018, we issued an aggregate of \$120.2 million principal amount of 2018 Notes that did not accrue interest. As of September 30, 2018, the fair value of the outstanding 2018 Notes was \$139.6 million. Pursuant to their terms, the 2018 Notes were settled in 7,856,176 shares of our common stock upon the closing of our IPO at a settlement price of \$15.30 per share, which is equal to 85% of the IPO price per share.

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:

	Nine Months Ended September 30, 2018
	(In thousands)
Net cash provided by (used in):	
Operating activities	\$ (23,172)
Investing activities	(319,410)
Financing activities	426,660
Net increase in cash, cash equivalents and restricted cash	<u>\$ 84,078</u>

Operating Activities

During the nine months ended September 30, 2018, cash used in operating activities of \$23.2 million was attributable to a net loss of \$181.0 million, partially offset by non-cash charges of \$146.0 million and a net change of \$11.2 million in our net operating assets and liabilities. The non-cash charge consisted primarily of acquired in-process research and development expense resulting

from the asset acquisition from Pfizer of \$109.4 million, change in fair value of convertible notes payable of \$19.4 million and \$12.7 million of stock-based compensation. The net change in operating assets and liabilities was primarily due to a \$12.7 million increase in accrued and other liabilities resulting from the timing of payments made to our collaboration partners and Pfizer and accrued professional and consulting services, a \$3.1 million increase in accounts payable driven by increased professional fees and partially offset by a \$3.1 million increase in prepaid expenses and other current assets and a \$1.5 million increase in other long-term assets.

Investing Activities

During the nine months ended September 30, 2018, cash used by investing activities of \$319.4 million was related to the purchase of investments of \$315.4 million, cash transaction costs of \$2.1 million incurred in the asset acquisition from Pfizer and the purchase of property and equipment of \$1.9 million.

Financing Activities

During the nine months ended September 30, 2018, cash provided by financing activities of \$426.7 million was related to net proceeds of \$299.3 million from the issuance of our Series A and A-1 convertible preferred stock, \$116.8 million in net proceeds from the issuance of the 2018 Notes and \$11.4 million from the issuance of common stock in connection with stock option exercises, partially offset by \$0.8 million cash payment of deferred offering costs incurred in connection with our IPO.

Contractual Obligations and Commitments

We did not have any contractual obligations, including debt obligations, capital lease obligations, operating lease obligations, purchase obligations or other long-term liabilities, as of December 31, 2017.

The following table summarizes our commitments and contractual obligations as of September 30, 2018:

	Payments Due by Period				
	Total	Remainder of 2018	2019 - 2020	2021 - 2022	2023 and After
	(in thousands)				
Contractual Obligations:					
Convertible Notes (1)	\$ 120,900	\$ —	\$ 120,900	\$ —	\$ —
Operating lease obligations (2)(3)	60,972	75	9,232	10,879	40,786
Total	\$ 181,872	\$ 75	\$ 130,132	\$ 10,879	\$ 40,786

- (1) In September 2018, we entered into a note purchase agreement pursuant in which we sold and issued \$120.2 million in aggregate principal amount of convertible promissory notes (2018 Notes). The 2018 Notes accrue no interest and have a maturity date of September 2019. Principal payments associated with the 2018 Notes are included in the above table. Pursuant to the terms of the 2018 Notes, the outstanding aggregate principal amount automatically converted into 7,856,176 shares of our common stock upon the closing of our IPO with no amount remaining outstanding on the 2018 Notes following the IPO.
- (2) In August 2018, we entered into an operating lease agreement for our new headquarters in South San Francisco. The lease term is 127 months beginning August 2018 through February 2029.
- (3) In October 2018, we entered into an operating lease agreement for office and laboratory space in South San Francisco near the headquarters. The lease has a term of ten years and four months commencing on November 1, 2018.

Commitments

Our commitments primarily consist of obligations under our agreements with Pfizer, Celectis 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 September 30, 2018, 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 the Prospectus, except for the determination of the fair value of our common stock, which is used in estimating the fair value of stock-based awards at grant date and the adoption of ASU No. 2016-02, *Leases (Topic 842)*, or ASU 2016-02 on January 1, 2018 as discussed below.

Prior to the IPO, our common stock was not publicly traded, therefore we estimated the fair value of our common stock as discussed in the Prospectus. Following our IPO, the closing sale price per share of our common stock as reported on the Nasdaq Global Select Market on the date of grant will be used to determine the exercise price per share of our share-based awards to purchase common stock.

We early adopted Accounting Standards Update (ASU) No. 2016-02, *Leases* as of January 1, 2018 in accordance with ASC 250, *Accounting Changes and Error Corrections*. Under this new lease standard, most leases are required to be recognized on the balance sheet as right-of-use assets and corresponding lease liabilities. In determining the present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date. The standard has been implemented using the required modified retrospective approach and we have elected not to apply either of the transitional practical expedients. As of September 30, 2018, the Company has one long-term operating lease that commenced on August 1, 2018. Consequently, the adoption of the standard did not have any impact on prior periods.

Emerging Growth Company Status

We are an emerging growth company, as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act 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.

Recent Accounting Pronouncements

Please refer to Note 2 to our unaudited condensed financial statements appearing under Part 1, Item 1 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, restricted cash and investments of \$399.2 million as of September 30, 2018, 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. Due to the short-term maturities of our cash equivalents and available-for-sale securities, and the low risk profile of our available-for-sale securities, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash equivalents and available-for-sale securities.

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

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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. We have marked with an asterisk () those risk factors that reflect changes from the similarly titled risk factors included in the Prospectus.*

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 currently do not have complete in-house resources to enable our allogeneic CAR T platform. We are heavily reliant on several support services from 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 build our own capabilities, 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 three months and nine months ended September 30, 2018, we reported a net loss of \$43.5 million and \$181.0 million, respectively. As of September 30, 2018, we had an accumulated deficit of \$181.0 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 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.

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 Collectis's TALEN gene-editing technology to inactivate a gene coding for TCR α , a key component of the natural antigen receptor of T cells, to cause the engineered T cells to be incapable of recognizing foreign antigens. Accordingly, when injected into a patient, the intent is for the engineered T cell not to recognize the tissue of the patient as foreign and thus avoid attacking the patient's tissue. In addition, we use TALEN gene editing 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 destroying the engineered allogeneic T cells.

We rely on an agreement with Collectis for rights to use TALEN and electroporation technology for 15 select targets, including BCMA, Flt3, CD70, DLL3 and other targets included in our pipeline. We also rely on Collectis, through our agreement with Servier, for rights to UCART19, ALLO-501 and potentially one additional target. We would need an additional license from Collectis or access to other gene-editing technology to research and develop product candidates directed at targets not covered by our existing agreements with Collectis and Servier. In addition, the Collectis gene-editing technology may fail to produce viable product candidates. Moreover, both Servier and Collectis may terminate our respective agreements in the event of a material breach of the agreements, or upon certain insolvency events. 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 in submitting an IND in the first half of 2019 for our second anti-CD19 allogeneic T cell product candidate, ALLO-501, for the treatment of patients with 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, or does not agree with our global development plan and budget for ALLO-501, our expenses may be greater than we currently expect and we may have difficulty progressing ALLO-501 in a timely manner.

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.

Collectis's TALEN technology involves a relatively new approach to gene editing, using sequence-specific DNA-cutting enzymes, or nucleases, to perform precise and stable modifications in the DNA of living-cells and organisms. Although Collectis has generated nucleases for many specific gene sequences, it has not created nucleases for all gene sequences that we may seek to target, and we may not be able to do so, which could limit the usefulness of this technology. This technology may also not be shown to be effective in clinical studies that Collectis, we or other licensees of Collectis technology may conduct, or may be associated with safety issues that may negatively affect our development programs.

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.

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.

In addition, the clinical study requirements of the FDA, 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. Unexpected clinical outcomes would significantly impact our business.

Our business is highly dependent on the success of UCART19. If we or Servier are unable to obtain approval for UCART19 and effectively commercialize UCART19 for the treatment of patients in its 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 candidate, UCART19. 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 is the first allogeneic product to be evaluated in the clinic, its failure, 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 if it 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 conduct the UCART19 trials in a timely and appropriate manner. Servier is currently experiencing manufacturing challenges, which will delay enrollment in the CALM and PALL clinical trials. Significant delays in enrollment 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.

All of our product candidates, including UCART19, 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 is our most advanced product candidate, and because our other product candidates are based on similar technology, 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.

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, infusion reaction, or prolong persistence of donor cells in the patients.

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 under in the Prospectus 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, 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 of UCART19.

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 UCART19 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 plan to submit 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 in 2019, and an IND in the first half of 2019 for ALLO-501 in the treatment of patients with R/R NHL. However, our timing of filing on these product candidates is dependent on further pre-clinical and manufacturing success. 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. 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 studies can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- 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 safety of patients receiving our product candidates is challenging, which could adversely affect our ability to obtain regulatory approval and commercialize.

For our ongoing clinical trials of UCART19 and in our planned clinical trials of other product candidates, Servier has contracted with and is expected to continue to 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, 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 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, our clinical trials will 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 UCART19, with Servier, and our other 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 and potentially as a first line therapy. 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 beyond the net proceeds from our IPO 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 can reduce the likelihood of a patient's immune system from rejecting engineered allogeneic T cells, and thereby may 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 other 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. To secure our own readily available source of anti-CD52 antibody, we are developing our own monoclonal anti-CD52 antibody, ALLO-647. We submitted a drug master file (DMF) to the FDA in August 2018 for ALLO-647. If the FDA activates the DMF, Servier will be authorized to reference the DMF in its IND proposing use of ALLO-647 in combination with UCART19 in clinical trials. There can be no assurance that the FDA will activate our DMF in a timely manner or at all. We plan to use ALLO-647 in our clinical trial of ALLO-501 and our clinical trial of ALLO-715. 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, which are subject to delayed enrollment due to UCART19 manufacturing challenges. 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 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 will result in T cells that will be safe and effective.

We plan to build a separate manufacturing facility with clinical and commercial supply manufacturing capabilities, but we have not identified a location for these activities or secured any space for these activities.

Our operations remain subject to review and oversight by the FDA and the FDA could object to our use of our manufacturing facility. We must first receive approval from the FDA prior to licensure to manufacture our product candidates, which we may never obtain. Even if approved, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current good manufacturing practices (cGMPs) and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review.

Our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates.

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. 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 may fail to manage the logistics of storing and shipping our 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 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 trial is currently being conducted in the United States, the United Kingdom and France, while the PALL clinical trial is currently being conducted in the United Kingdom, Belgium and France, 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 in both the CAR and TCR technology space 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.

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 that vest over time. The value to employees of stock options 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 November 15, 2018, we had 90 employees, all of whom are full-time. 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 continue 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. 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 the Collaboration and License Agreement with Cellectis and the 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.

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 September 30, 2018, we had \$398.3 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 require additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate.

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 or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and the systems of our CROs, contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. 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.

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 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 and state 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. 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’ 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 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 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 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, 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.

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. Assuming we obtained clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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. 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, 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.

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 is currently experiencing manufacturing challenges, which will delay enrollment in the CALM and PALL clinical trials. 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 all other aspects of the supply, including planning, CMO oversight, disposition and distribution logistics.

Although we expect to secure our own clinical 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.
- 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.
- 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 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. 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 Collectis, 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. In addition, those 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 do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing.

In addition, 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.

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, including with respect to chain of identity and chain of custody of 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 applying them on a patient by patient basis 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.*

We plan to support the completion of the CALM and PALL clinical trials, which are subject to delayed enrollment due to UCART19 manufacturing challenges. If and when the CALM and PALL clinical trials are completed and, assuming positive data, we expect UCART19 to be advanced to potential registrational trials, CALM II and PALL II. 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 CALM II will be designed to evaluate the efficacy of UCART19 in an open-label, international, non-comparative, two-stage, pivotal, multicenter, single-arm clinical trial in adult patients with R/R ALL who have exhausted available treatment options, and PALL II will be designed as an open-label, international, non-comparative, two-stage, pivotal clinical trial of pediatric patients with R/R ALL aged from three months up to less than 18 years. If the results are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for UCART19. 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 UCART19. 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 patient's that have failed or who are ineligible for autologous therapy, which are extremely difficult patients to treat and patients with advanced and aggressive cancer, and our product candidates may fail to improve outcomes for such patients.

The FDA may grant accelerated approval for our product candidates and, as a condition for accelerated approval, the FDA may require a sponsor of a drug or biologic receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. We believe our accelerated approval strategy is warranted given the limited alternatives for patients with R/R ALL, 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 our clinical trials and the FDA may not accept the use of ALLO-647 in our clinical trials in a timely manner or at all. For instance, the FDA may not accept comparability data to alemtuzumab. 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 UCART19 and our other allogeneic T cell product candidates.

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 inspect our commercial manufacturing facility and may not approve our 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.

A Breakthrough Therapy Designation by the FDA, 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 a Breakthrough Therapy Designation for our product candidates if the clinical data support such a designation for one or more product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to drugs considered for approval under non-expedited the FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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. Increased negative public opinion or more restrictive government regulations in response thereto, 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 and pricing 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 as part of a tax reform bill. Further, 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. Moreover, the Bipartisan Budget Act of 2018 (BBA), among other things, amends 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". More recently, in July 2018, CMS announced that it is suspending 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 pending the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Congress is continuing to consider legislation that would alter other aspects of the Affordable Care Act. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear.

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 proposed and enacted federal and state legislation 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. The Department of Health and Human Services (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. While some proposed measures will 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 Collectis. These licenses may be terminated upon certain conditions. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. For example, we are dependent on our license with Collectis for gene-editing technology that is necessary to produce our engineered T cells. In addition, Servier licenses some of the intellectual property rights they are licensing to us. 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 Collectis 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.

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 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 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, to develop 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.

Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. 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 our 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 may be subject to claims challenging the inventorship of our patents and other intellectual property.

We 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 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 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 recently completed IPO, 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;
- 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 internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- 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 may be required to incur 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.

Substantially all of our pre-IPO stockholders are subject to lock-up agreements with the underwriters of our IPO that restrict their ability to transfer shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock until April 9, 2019. The lock-up agreements limit the number of shares of common stock that may be sold immediately following our IPO. As of November 15, 2018, there are 121,482,671 shares of stock outstanding, including 25,717,676 shares issued but subject to repurchase, as described under Note 10 and to our financial statements appearing elsewhere in this report. Subject to certain limitations, approximately 100,782,671 shares will become eligible for sale upon expiration of the lock-up period, a portion of which will be subject to repurchase. Sales of stock by these stockholders could have a material adverse effect on the trading price 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, subject to the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction 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 and the lock-up agreements described above.

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. 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 to our employees, directors and consultants.

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2018 Plan is 9,335,850 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, beginning on January 1, 2019 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 the Prospectus entitled “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 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.

Sales of Unregistered Securities

Set forth below is information regarding securities issued and options granted by us since November 30, 2017 that were not registered under the Securities Act. Also included is the consideration, if any, received by us, for such securities and options and information relating to the Securities Act, or rule of the SEC, under which exemption from registration was claimed.

(1) In December 2017, we issued and sold 26,249,993 shares of common stock to our founders pursuant to a series of stock purchase agreements at a purchase price of \$0.001 per share, and received aggregate gross proceeds of \$5,000.

(2) In April 2018, we entered into a Series A and A-1 preferred stock purchase agreement with various investors, pursuant to which we issued and sold to such investors an aggregate of 7,557,990 shares of our Series A convertible preferred stock and 998,225 shares of our Series A-1 convertible preferred stock at a purchase price of \$35.06 per share, and received aggregate gross proceeds of approximately \$300 million. Half of this funding was received in April 2018 and the remainder was received in July and August 2018.

(3) In April 2018, we entered into an asset contribution agreement with Pfizer Inc., pursuant to which we issued and sold to Pfizer an aggregate of 3,187,772 shares of our Series A-1 convertible preferred stock in exchange for certain assets and rights relating to investigational drugs.

(4) In June 2018, we granted stock options under our amended and restated 2018 equity incentive plan, as amended (the Prior Plan), to purchase up to an aggregate of 8,808,975 shares of our common stock to our employees, directors and consultants, at a weighted-average exercise price of \$2.27 per share. Subsequent to June 30, 2018, we granted stock options under the Prior Plan to purchase up to an aggregate of 2,347,275 shares of our common stock to our employees and consultants, at a weighted-average exercise price of \$6.87 per share. From June 2018 to the effective date of this registration statement, 5,020,575 shares of common stock were issued upon the exercise of options granted to employees, directors and consultants and the payment of \$11,370,407 to us was made.

(5) In September 2018, we entered into a note purchase agreement with certain individual and institutional accredited investors, pursuant to which we sold and issued \$120.2 million aggregate principal amount of 2018 Notes in exchange for \$116.9 million in net cash proceeds.

Upon the closing of our IPO, the shares of Series A and A-1 preferred stock described in paragraphs (2) and (3) above were automatically converted into an aggregate of 61,655,922 shares of our common stock, and the 2018 Notes described in paragraph (4) above were automatically converted into an aggregate of 7,856,176 shares of our common stock. The offers, sales and issuances of the securities described in paragraphs (1) through (3) and (5) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) (or Regulation D promulgated thereunder) in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D. No underwriters were involved in these transactions.

The offers, sales and issuances of the securities described in paragraph (4) were deemed to be exempt from registration under the Securities Act in reliance on either Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or Section 4(a)(2) in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under the Prior Plan.

Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

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 November 15, 2018, 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	<u>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.</u>
3.2	<u>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.</u>
4.1	Reference is made to Exhibits <u>3.1</u> and <u>3.2</u> .
4.2	<u>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)), originally filed with the SEC on September 14, 2018).</u>
4.3	<u>Investors Rights Agreement, dated April 6, 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)), originally filed with the SEC on September 14, 2018).</u>
10.1+	<u>Allogene Therapeutics, Inc. Amended and Restated 2018 Equity Incentive Plan and Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise, Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement thereunder (incorporated by reference to Exhibit 99.2 to the Registrant's Registration Statement on Form S-8 (File No. 333-227965)), filed with the SEC on October 24, 2018).</u>
10.2+	<u>Allogene Therapeutics, Inc. 2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 (File No. 333-227965)), filed with the SEC on October 24, 2018).</u>
10.3+	<u>Allogene Therapeutics, Inc. 2018 Change in Control and Severance Benefit Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333)), filed with the SEC on October 2, 2018).</u>
10.4+	<u>Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333)), filed with the SEC on October 2, 2018).</u>
10.5	<u>Lease, dated August 1, 2018, by and between the Registrant and Britannia Pointe Grand Limited Partnership (incorporated by reference to Exhibit 10.13 (originally filed as Exhibit 10.11) to the Registrant's Registration Statement on Form S-1 (File No. 333-227333), as amended), originally filed with the SEC on September 14, 2018).</u>
31.1	<u>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.</u>
31.2	<u>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.</u>
32.1	<u>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.</u>
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.

+ Indicates management contract or compensatory plan.

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: November 21, 2018

By: /s/ David Chang

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

Date: November 21, 2018

By: /s/ Eric Schmidt

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

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

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

1. I have reviewed this 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: November 21, 2018

/s/ David Chang

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

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

I, Eric Schmidt, Ph.D., certify that:

1. I have reviewed this 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: November 21, 2018

/s/ Eric Schmidt

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

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

In connection with the quarterly report of Allogene Therapeutics, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2018 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: November 21, 2018

/s/ David Chang

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

Date: November 21, 2018

/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.