

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 10-K**

(Mark One)

**ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
For the fiscal year ended December 31, 2019

OR

**TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**  
FOR THE TRANSITION PERIOD FROM TO  
Commission File Number 001-38693

**Allogene Therapeutics, Inc.**

(Exact name of Registrant as specified in its Charter)

Delaware  
(State or other jurisdiction  
of incorporation or organization)

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

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

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

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, Par Value \$0.001 Per Share	ALLO	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes  No

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant as of June 28, 2019 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately \$1,601 million based on the closing price of the registrant's common stock on June 28, 2018 of \$26.85 per share, as reported by The Nasdaq Global Select Market.

The number of shares of Registrant's Common Stock outstanding as of February 24, 2020 was 124,906,945.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Definitive Proxy Statement relating to the 2020 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2019, are incorporated by reference into Part III of this Report.

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Unless the context requires otherwise, references in this report to “Allogene,” “we,” “us” and “our” refer to Allogene Therapeutics, Inc., and references in this report to “Servier” collectively refer to Les Laboratoires Servier SAS and Institut de Recherches Internationales Servier SAS.

### **SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS**

This Annual Report on Form 10-K contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the success, cost, timing and potential indications of our product development activities and clinical trials;
- the timing of our planned investigational new drug application submissions to the U.S. Food and Drug Administration for our product candidates;
- the timing of the initiation, enrollment and completion of planned clinical trials in the United States and foreign countries;
- our ability to obtain and maintain regulatory approval of our product candidates in any of the indications for which we plan to develop them, and any related restrictions, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations, including funding necessary to complete the clinical trials of any of our product candidates;
- our plans to research, develop and commercialize our product candidates;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- the size of the markets for our product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our product candidates;
- the rate and degree of market acceptance of our product candidates;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- our ability to contract with and the performance of our and our collaborators’ third-party suppliers and manufacturers;
- our ability to develop and successfully operate our own manufacturing facility;
- the success of competing therapies that are or become available;
- our ability to attract and retain key scientific or management personnel;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing;
- our use of cash and other resources; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others.

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this report and are subject to risks and uncertainties. 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 report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We discuss many of the risks associated with the forward-looking statements in this report in greater detail under the heading “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should carefully read this report and the documents that we reference in this report and have filed as exhibits to the Form 10-K, of which this report is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this report by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in any forward-looking statements, whether as a result of new information, future events or otherwise.

### **Trademarks and Trade names**

This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

## PART I

### Item 1. Business

#### 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.

Chimeric antigen receptor (CAR) T cell therapy, a form of cancer immunotherapy, has emerged as a revolutionary and potentially curative therapy for patients with hematologic cancers, including refractory cancers. In 2017, the first two autologous anti-CD19 CAR T cell therapies, Kymriah, developed by Novartis International AG (Novartis), and Yescarta, developed by Kite Pharma, Inc. (Kite), were approved by the U.S. Food and Drug Administration (FDA) for the treatment of relapsed/refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL) (Kymriah) and R/R large B-cell lymphoma (Yescarta). Autologous CAR T cell therapies are manufactured individually for the patient's use by modifying the patient's own T cells outside the body, causing the T cells to express CARs. The entire manufacturing process is dependent on the viability of each patient's T cells and takes approximately two to four weeks. As seen in the registrational trials for Kymriah and Yescarta, up to 31% of intended patients ultimately did not receive treatment primarily due to interval complications from the underlying disease during manufacturing or manufacturing failures.

Our allogeneic approach involves engineering healthy donor T cells, which we believe will allow for the creation of an inventory of off-the-shelf products that can be delivered to a larger portion of eligible patients throughout the world. These potential benefits led our Executive Chairman, Arie Belldegrun, M.D., FACS, who was previously the Chairman and Chief Executive Officer at Kite, and our President and Chief Executive Officer, David Chang, M.D., Ph.D., previously Chief Medical Officer and Executive Vice President of Research and Development at Kite, to found our company with the driving purpose of accelerating the development of allogeneic CAR T cell therapies.

We have multiple clinical trials ongoing and have a deep pipeline to further the research and development of allogeneic CAR T cell product candidates in both hematological malignancies and solid tumors. We believe our management team's experience in immuno-oncology and specifically in CAR T cell therapy will help drive the rapid development and, if approved, the commercialization of potentially curative therapies for patients with aggressive cancer.

#### Our Approach

Our allogeneic T cell development strategy has four key pillars: (1) developing product candidates to minimize the risk of graft-versus-host disease (GvHD), a condition where allogeneic T cells can recognize the patient's normal tissue as foreign and cause damage, (2) creating a window of persistence that may enable allogeneic T cells to expand in patients, (3) building a leading manufacturing platform and (4) leveraging next generation technologies to improve the functionality of allogeneic CAR T cells.

We use Collectis, S.A. (Collectis), TALEN gene-editing technology with the goal of limiting the risk of GvHD by engineering T cells to lack functional T cell receptors (TCRs) that are no longer capable of recognizing a patient's normal tissue as foreign. With the goal of enhancing the expansion and persistence of our engineered allogeneic T cells, we use TALEN to inactivate the CD52 gene in donor T cells and an anti-CD52 monoclonal antibody to deplete CD52 expressing T cells in patients while sparing the therapeutic allogeneic T cells. We believe this enables a window of persistence for the infused allogeneic T cells to actively target and destroy cancer cells. We are also developing ALLO-647, our own anti-CD52 monoclonal antibody. Our off-the-shelf approach is dependent on state-of-the-art manufacturing processes, and we are building a technical operations organization with fully integrated in-house expertise in clinical and commercial engineered T cell manufacturing. In February 2019, we entered into a lease to build our own cell therapy manufacturing facility in Newark, California, and we expect to commence manufacturing at our facility in 2021. Finally, we plan to leverage next generation technologies to develop more potent product candidates and to develop product candidates from a renewable cell source. We believe next generation technologies will also allow us to develop allogeneic T cell therapies for the treatment of solid tumors, which to date have been difficult to treat because of the lack of validated targets and tumor microenvironments that can impair the activity of T cells.

## Our Pipeline

We are currently developing a pipeline of multiple allogeneic CAR T cell product candidates utilizing protein engineering, gene editing, gene insertion and advanced proprietary T cell manufacturing technologies. Several of our most advanced product candidates, including UCART19, ALLO-501 and ALLO-501A, are engineered allogeneic CAR T cell therapies that target CD19, a protein expressed on the cell surface of B cells and a validated target for B cell driven hematological malignancies. We are also developing engineered allogeneic CAR T cell product candidates for multiple myeloma, other blood cancers and solid tumors. Our pipeline is represented in the diagram below.

CATEGORY	PROGRAM	PRE-CLINICAL	PHASE 1	PHASE 2/3 <sup>1</sup>	
Hematological Malignancies	CD19	UCART19 (ALL) <sup>2</sup>	████████████████████		
		ALLO-501 (NHL) <sup>2 3</sup>	████████████████████		
		ALLO-501A (NHL) <sup>2 3</sup>	██████████████		
	BCMA	ALLO-715 (MM)	████████████████████		
		ALLO-715 + nirogacestat (MM) <sup>5</sup>	██████████████		
		ALLO-605 (TurboCAR™/MM)	██████████████		
		ALLO-316 (CD70)	██████████████		
Solid Tumors	ALLO-819 (FLT3/AML)	██████████████			
	ALLO-316 (CD70/RCC)	██████████████			
	DLL3 (SCLC)	██████████████			
Lymphodepletion Agent	Multiple Undisclosed Targets	██████████			
		ALLO-647 (Anti-CD52 mAb) <sup>4</sup>	████████████████████		

<sup>1</sup> Phase 3 may not be required if Phase 2 is registrational.

<sup>2</sup> Servier will hold ex-US commercial rights. Servier is the sponsor of the UCART19 trials.

<sup>3</sup> Allogene is the sponsor of the ALLO-501 trial and plans to sponsor a trial for ALLO-501A.

<sup>4</sup> ALLO-647 intended to enable expansion and persistence of allogeneic CAR T product candidates.

<sup>5</sup> Allogene sponsored trial in combination with SpringWorks Therapeutics, Inc.

Our lead product candidates include:

- UCART19.** Our collaboration partner, Servier, is sponsoring two Phase 1 clinical trials of UCART19 in patients with R/R ALL, one for adult patients (the CALM trial) and one for pediatric patients (the PALL trial). In December 2018, interim results from 21 patients in the CALM and PALL clinical trials were presented at the 60th American Society of Hematology (ASH) Annual Meeting. As of October 23, 2018, 67% (14/21) of patients achieved complete remission (CR) or complete remission with incomplete blood recovery (CRi). Eighty-two percent (14/17) of patients who received a lymphodepletion regimen consisting of fludarabine, cyclophosphamide and an anti-CD52 monoclonal antibody (FCA) achieved a CR/CRi. In the four patients who received fludarabine and cyclophosphamide (FC) only, there was no evidence of UCART19 cell expansion and no responses were observed. We believe the interim data of UCART19 suggest an anti-CD52 antibody is an important addition to the lymphodepletion regimen for allogeneic CAR T cell expansion, and we are progressing the development of our own anti-CD52 antibody, ALLO-647, as described below. The most common adverse events were related to cytokine release syndrome (CRS) and were generally manageable. Two mild (Grade 1) GvHD cases in the skin were observed and resolved. Subject to the continued advancement of the Phase 1 trials, we expect UCART19 to be advanced to potential registrational trials in 2021. See “—Product Pipeline and Development Strategy—UCART19—Pooled CALM and PALL Clinical Findings—Interim Safety” for more information regarding adverse events.

- *ALLO-501*. We are sponsoring a Phase 1 clinical trial (the ALPHA trial) of ALLO-501 in patients with the most common R/R non-Hodgkin lymphoma (NHL) subtypes. This includes R/R large B-cell lymphoma and R/R follicular lymphoma (FL). In January 2019, the FDA cleared our investigational new drug application (IND) for the ALPHA trial, and we initiated the trial in the second quarter of 2019. We expect to report initial data from the trial in the second quarter of 2020.
- *ALLO-501A*. We plan to use the clinical data from ALLO-501 to accelerate the development of the second-generation version of ALLO-501, known as ALLO-501A. We have removed rituximab recognition domains in ALLO-501A, which we believe will potentially facilitate treatment of more patients, as rituximab is a typical part of a treatment regimen for a patient with NHL. In December 2019, the FDA cleared our IND to initiate a Phase 1/2 clinical trial for ALLO-501A (the ALPHA2 trial) and we plan to initiate the trial in the second quarter of 2020, subject to completing the manufacturing of ALLO-501A. The Phase 1 portion of the ALPHA2 trial is designed to assess the safety and tolerability at increasing dose levels of ALLO-501A in patients with R/R large B-cell lymphoma or transformed FL.
- *ALLO-715*. We are sponsoring a Phase 1 clinical trial (the UNIVERSAL trial) of ALLO-715, an allogeneic CAR T cell product candidate targeting B-cell maturation antigen (BCMA), in adult patients with R/R multiple myeloma. In May 2019, the FDA cleared our IND for the UNIVERSAL trial, and we initiated the trial in the third quarter of 2019. We expect to report initial data from the trial in the fourth quarter of 2020. In addition, in January 2020, we entered into a clinical trial collaboration agreement with SpringWorks Therapeutics, Inc. (SpringWorks) to evaluate ALLO-715 in combination with SpringWorks' investigational gamma secretase inhibitor (GSI), nirogacestat, in patients with R/R multiple myeloma. We plan to initiate this combination trial in the second half of 2020, subject to regulatory clearance.
- *ALLO-647*. We are developing an anti-CD52 monoclonal antibody, ALLO-647, which is designed to be used prior to infusing our other product candidates as part of the lymphodepletion regimen. ALLO-647 may be able to reduce the likelihood of a patient's immune system rejecting the engineered allogeneic T cells for a sufficient period of time to enable a window of persistence during which our engineered allogeneic T cells can actively target and destroy cancer cells. We are currently utilizing ALLO-647 in the ALPHA trial and UNIVERSAL trial, and plan to utilize ALLO-647 in the ALPHA2 trial.

## **Our History and Team**

We believe we have established a leadership position in allogeneic T cell therapy. In April 2018, we acquired certain assets from Pfizer Inc. (Pfizer), including strategic license and collaboration agreements and other intellectual property related to the development and administration of allogeneic CAR T cells for the treatment of cancer. We have an exclusive collaboration with Servier to develop and commercialize UCART19, ALLO-501 and ALLO-501A, and we hold the commercial rights to these product candidates in the United States. We also have an exclusive worldwide license from Collectis to its TALEN gene-editing technology for the development of allogeneic T cell product candidates directed against 15 different cancer antigens. Our collaboration with Servier is intended to give us access to TALEN gene-editing technology for all product candidates under our collaboration with Servier. In connection with the Pfizer asset acquisition, we hired a team of employees from Pfizer, who are primarily research and technical operation employees and were leading the research and development of our product candidates and next generation gene engineering and cell engineering technologies at Pfizer.

Our world-class management team has significant experience in immuno-oncology and in progressing products from early stage research to clinical trials, and ultimately to regulatory approval and commercialization. In particular, Dr. Belldegrün's experience in T cell therapy dates back to his time at the National Cancer Institute as a research fellow in surgical oncology and immunotherapy with Steven Rosenberg, M.D., Ph.D, a recognized pioneer in immuno-oncology. Our President and Chief Executive Officer, Dr. Chang, served as Executive Vice President of Kite and held senior leadership roles at Amgen, Inc. (Amgen). Moreover, both Dr. Belldegrün and Dr. Chang led the development and approval of Yescarta at Kite. Additionally, our Chief Technical Officer, Alison Moore, Ph.D., was previously Senior Vice President, Process Development at Amgen, where she led the development, deployment and oversight of manufacturing for approximately 80 multi-modality assets. Dr. Moore has over 25 years of experience in biotechnology, including in the immuno-oncology space leading process development of Amgen's comprehensive bi-specific T cell engager production platform. In September 2019, Rafael Amado, M.D., joined us as our Executive Vice President of Research and Development and Chief Medical Officer. Dr. Amado has more than 15 years of biotechnology and pharmaceutical industry experience leading clinical and research teams, and he most recently served as President, Research and Development, at Adaptimmune Therapeutics plc, a T cell therapy company, from August 2018 to August 2019, and as Chief Medical Officer from March 2015.

## **Our Strategy**

Our goal is to maintain and build upon our leadership position in allogeneic T cell therapy. We plan to rapidly develop and, if approved, commercialize allogeneic T cell products for the treatment of cancer that can be delivered faster, more reliably and at greater scale than autologous T cell therapies. We believe achieving this goal could result in allogeneic T cell therapy becoming a standard of care in cancer treatment and enable us to make potentially curative therapies more readily accessible to more patients throughout the world. Key elements of our strategy include:

- **Capitalize on a validated target and our leadership in engineered allogeneic anti-CD19 CAR T cell product candidates.** Autologous anti-CD19 CAR T cell therapies, such as Kymriah and Yescarta, have emerged as potentially curative therapies for B-cell lymphomas and leukemias. We believe developing allogeneic CAR T cell product candidates targeting CD19 is the next frontier in delivering potentially curative therapies against B-cell lymphomas and leukemias, including NHL and ALL. We plan to support Servier in advancing the CALM and PALL trials in R/R ALL. We also expect to report initial data from the ALPHA trial in R/R NHL in the second quarter of 2020, and build on this data by rapidly advancing the clinical development of ALLO-501A. We believe having the first anti-CD19 allogeneic CAR T cell product candidate in the clinic gives us a leadership advantage in efforts to obtain approval of and commercialize anti-CD19 allogeneic CAR T cell product candidates in B-cell lymphoma and leukemia indications.
- **Expand our leadership position within hematologic indications.** In addition to UCART19 and ALLO-501A, we plan to advance our near-term pipeline against additional hematological targets where there remains a high unmet need. For example, we are developing ALLO-715, an allogeneic CAR T cell product candidate targeting BCMA. We believe BCMA is a promising target, as early results from clinical trials of third-party autologous CAR T cell therapeutic candidates targeting BCMA have been compelling. Our Phase 1 clinical trial of ALLO-715 for the treatment of patients with R/R multiple myeloma is the first to study an allogeneic CAR T therapy targeting BCMA and we plan to report initial data from the trial in the fourth quarter of 2020. In addition, we plan to initiate a combination trial of ALLO-715 with SpringWorks' nirogacestat, in patients with R/R multiple myeloma in the second half of 2020, subject to regulatory clearance. We believe nirogacestat has the potential to increase the cell surface density of BCMA and reduce levels of soluble BCMA, thereby enhancing the activity of ALLO-715. We also plan to develop additional allogeneic T cell product candidates targeting other antigens found on hematologic malignancies, including ALLO-316 targeting CD70 and ALLO-819 targeting FLT3, each for the treatment of acute myeloid leukemia (AML).
- **Build state-of-the-art gene engineering and cell manufacturing capabilities.** Manufacturing allogeneic T cell product candidates involves a series of complex and precise steps. We believe a critical component to our success will be to leverage and expand our proprietary manufacturing know-how, expertise and capacity. In February 2019, we entered into a lease for approximately 118,000 square feet to develop a state-of-the-art cell therapy manufacturing facility in Newark, California. We plan to phase the build-out of the facility, and expect to complete the build-out of the majority of the facility in the second half of 2020 and initiate manufacturing under current good manufacturing practices (cGMP) in 2021. We believe establishing our own fully integrated manufacturing operations and infrastructure will allow us to improve the manufacturing process, limit our reliance on contract manufacturing organizations (CMOs) and more rapidly advance product candidates.
- **Leverage next generation technologies to advance our platform and expand into solid tumor indications with high unmet need.** We have a broad portfolio of solid tumor targets, including CD70 for the treatment of renal cell cancer and DLL3 for the treatment of small cell lung cancer and other aggressive neuroendocrine tumors. We plan to leverage next generation technologies to make more potent allogeneic CAR T cells and improve the characteristics of our product candidates. For example, we are developing TurboCARs, which include a CAR T cell-specific cytokine signal designed to augment the potency and durability of allogeneic T cells. In collaboration with Notch Therapeutics Inc. (Notch), we are researching and developing a process for production of product candidates derived from induced pluripotent stem cells (iPSCs). We believe iPSCs may provide renewable starting material for our allogeneic CAR T cell product candidates that could allow for improved efficiency of gene editing, greater scalability of supply, product homogeneity and more streamlined manufacturing. In addition, we continually survey the scientific and industry landscape for opportunities to license, partner or acquire technologies that may help us advance current or new T cell therapies for the benefit of patients.

## Allogeneic T Cell Therapy

### *The Immune System and Cancer*



White blood cells are a component of the immune system and are responsible for defending the body against infectious pathogens and other foreign material. T cells are a type of white blood cell and are involved in both sensing and killing infected or abnormal cells, including cancer cells, as well as coordinating the activation of other cells in an immune response.

T cells can be distinguished from other white blood cells by T cell receptors present on their cell surface. These receptors contribute to tumor surveillance by directing T cells to recognize and destroy cancerous cells. When T cells with cancer-specific receptors are absent, present in low numbers, of poor quality or rendered inactive by suppressive mechanisms, cancer may grow and spread. In addition, standard of care treatments, such as chemotherapy regimens, as well as disease specific factors can damage the patient's immune system, thereby inhibiting the ability of T cells to kill cancer.

### ***Engineered T Cell Therapies***

Engineered T cell therapy is a type of immunotherapy treatment whereby human T cells are removed from the body and engineered to express CARs which, when infused into a patient, may recognize and destroy cancer cells in a targeted manner.

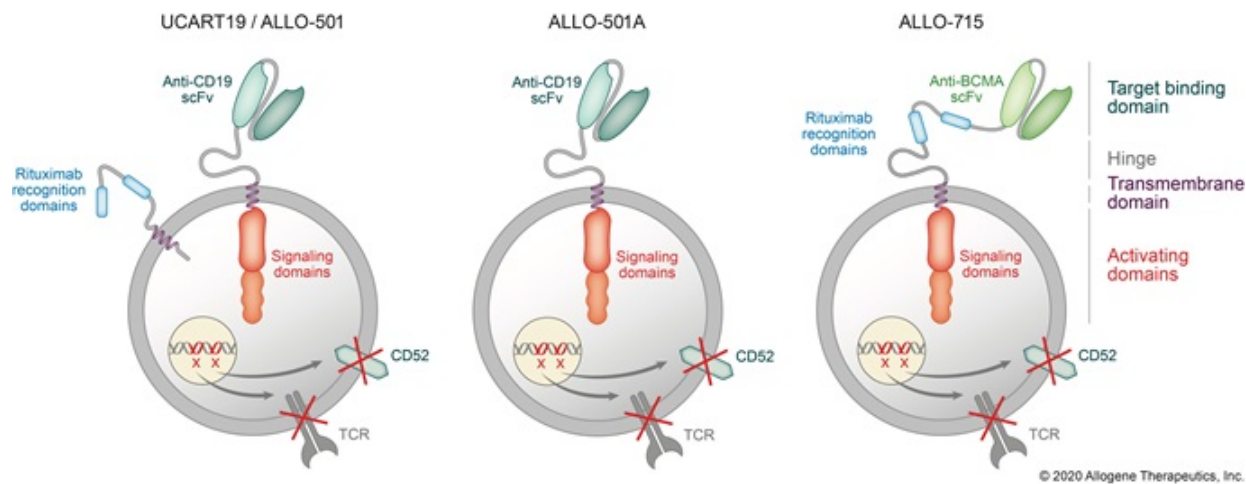
#### ***Chimeric Antigen Receptors (CARs)***

CARs are engineered molecules that, when present on the surface of a T cell, enable the T cell to recognize specific proteins or antigens that are present on the surface of other cells. The CAR in UCART19, ALLO-501, ALLO-501A and ALLO-715 is comprised of a single chain protein that contains the following elements:

- ***Target Binding Domain:*** At one end of the CAR is a target binding domain that is specific to a target antigen. This domain extends out onto the surface of the engineered T cell, where it can recognize the target antigens. The target binding domain consists of a single-chain variable fragment (scFv) of an antibody comprising variable domains of heavy and light chains joined by a short linker.
- ***Transmembrane Domain and Hinge:*** This middle portion of the CAR links the scFv target binding domain to the activating elements inside the cell. This transmembrane domain “anchors” the CAR in the cell's membrane. In addition, the transmembrane domain may also interact with other transmembrane proteins that enhance CAR function. The hinge domain, which extends to the exterior of the cell, connects the transmembrane domain to scFv and provides structural flexibility to facilitate optimal binding of scFv to the target antigen on the cancer cell's surface.
- ***Activating Domains:*** The other end of transmembrane domain, inside the T cell, is connected to two contiguous domains responsible for activating the T cell when the CAR binds to the target cell. The CD3 zeta domain delivers an essential primary signal within the T cell, and the 41BB domain delivers an additional, co-stimulatory signal. Together, these signals trigger T cell activation, resulting in proliferation of the CAR T cells and killing of the cancer cell. In addition, activated CAR T cells stimulate the local secretion of cytokines and other molecules that can recruit and activate additional immune cells to potentiate killing of the cancer cells.

In addition to the domains described above, ALLO-715 possesses two rituximab-recognition domains between the scFv and the hinge which allow it to be recognized and eliminated by rituximab. UCART19 and ALLO-501 possess rituximab recognition domains in a separate polypeptide termed RQR8 that is co-expressed with the CAR. We have removed rituximab recognition domains in ALLO-501A, which we believe will potentially facilitate treatment of more patients, as rituximab is a typical part of a treatment regimen for a patient with NHL.

The figure below shows the constructs that support our lead programs: UCART19, ALLO-501, ALLO-501A and ALLO-715.



## Allogeneic T Cell Therapies: The Next Revolution

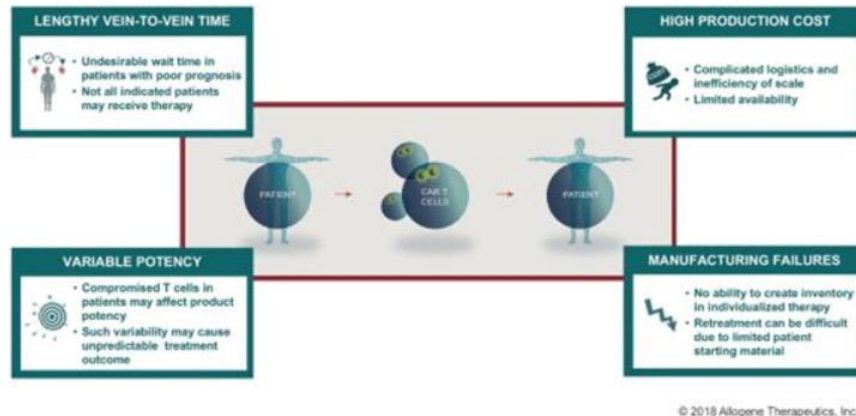
There are two primary approaches to engineered T cell therapy: autologous and allogeneic. Autologous therapies use engineered T cells derived from the individual patient, while allogeneic therapies use engineered T cells derived from healthy donor T cells.

The autologous approach, pioneered by Novartis and Kite, has been highly successful in engineering patients' immune systems to fight cancer, in particular CD19 positive cancers, resulting in significant remission rates. Autologous products are manufactured by first collecting a patient's white blood cells, through a process known as leukapheresis, separating the T cells from the patient's blood sample and proliferating the isolated T cells. After the cells have multiplied, the CAR construct is virally transduced into the T cells and the engineered T cells are then propagated until a sufficient number of cells are available for infusion into the patient. Finally, the engineered T cells are frozen, and then shipped back to the clinical center for administration to the patient. The process from leukapheresis to delivery to the clinical center takes approximately two to four weeks.

While the autologous approach has been revolutionary, demonstrating compelling efficacy in many patients, it is burdened by the following key limitations:

- **Lengthy Vein-to-Vein Time.** Due to the individualized manufacturing process, patients must wait approximately two to four weeks to be treated with their engineered cells. As a result, in the registrational trials for Yescarta and Kymriah, up to 31% of intended patients ultimately did not receive treatment primarily due to interval complications from the underlying disease during manufacturing or manufacturing failures.
- **Variable Potency.** In many cases, patients have T cells that have been damaged or weakened due to prior chemotherapy or hematopoietic stem-cell transplant. Compromised T cells may not proliferate well during manufacturing or may produce cells with insufficient potency that cannot be used for patient treatment, resulting in manufacturing failures, or that can show poor expansion and activity in patients. In addition, the individualized nature of autologous manufacturing, together with the variability in patients' T cells, may lead to variable potency of manufactured T cells, and this variability may cause unpredictable treatment outcomes.
- **Manufacturing Failures.** Autologous cell manufacturing sometimes encounters production failures. This can mean that a patient never receives treatment, as additional patient starting material may not be available or the patient may no longer be eligible due to advanced disease. Furthermore, retreatment can be difficult due to a limited supply of usable patient starting material.
- **High Production Cost.** The delivery of autologous T cell therapy is complicated due to the individualized nature of manufacturing, which allows only one patient to be treated from each manufacturing run and requires dedicated infrastructure to maintain a strict chain of custody and chain of identity of patient-by-patient material collection, manufacturing and delivery. The complex logistics add significant cost to the process and limit the ability to scale. Additionally, the collection of T cells through leukapheresis from each individual patient results in a time consuming

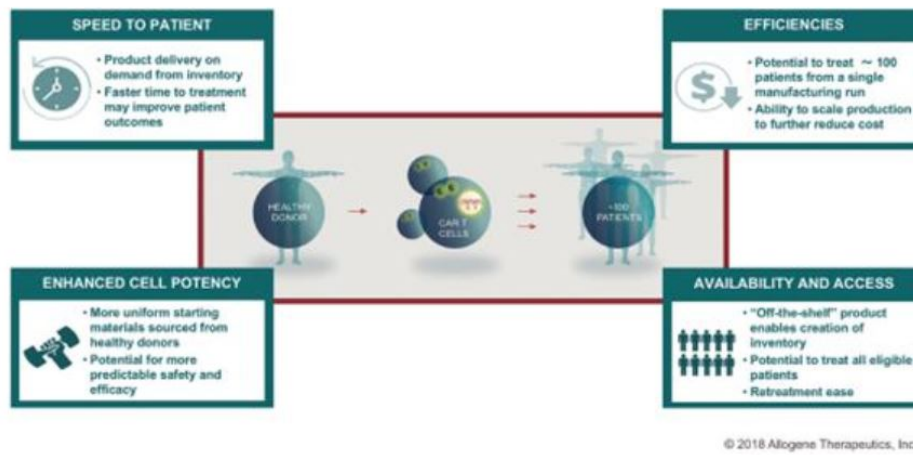
and costly step in the autologous process. In part due to these logistics, autologous treatment is currently only available at select centers.



Allogeneic engineered T cells are manufactured in a similar manner as autologous, but our manufacturing has two key differences: (1) our allogeneic T cells are derived from healthy donors, not cancer patients, and (2) our allogeneic T cells are genetically engineered to minimize the risk of GvHD and enable a window of persistence in the patient.

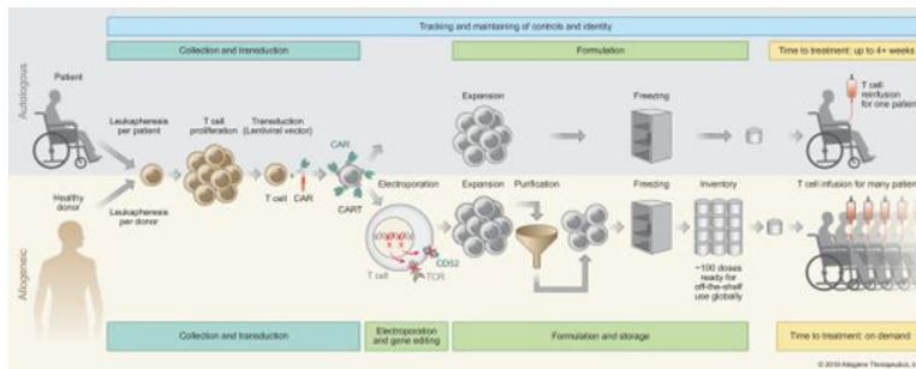
Our approach is designed to provide the same intended curative outcome as autologous therapy, while offering the following potential key advantages:

- **Availability and Access.** Starting with T cells from a healthy donor, we believe that at scale we can manufacture approximately 100 doses of allogeneic product that could be used in any eligible patient. Because our allogeneic product candidates are designed to be frozen and available off-the-shelf, they could potentially be readily shipped and administered to patients. We believe having an inventory of off-the-shelf allogeneic T cell products can also facilitate delivering multiple product doses to a patient over time as well as enable treatment with multiple different engineered allogeneic T cell products directed to different cancer targets in a patient.
- **Speed to Patient.** Many patients with aggressive cancer or rapidly progressing cancer that is refractory to existing therapies may not have multiple weeks to wait for autologous T cell treatment. Our allogeneic approach has the potential to create off-the-shelf product inventory, which could enable dosing of patients within days of prescription. This would represent a significant reduction in patient wait time, potentially allowing the treatment of patients who are too sick to wait for the autologous therapy, and could improve patient outcomes.
- **Enhanced Cell Consistency and Potency.** Our manufacturing process produces therapies from selected, screened and tested healthy donors. Healthy donor T cells are potentially superior for engineered cellular therapy as compared to T cells from patients who have undergone prior chemotherapy or hematopoietic stem-cell transplant, which can damage or weaken T cells. In addition, greater consistency of the product may yield more predictable treatment outcomes.
- **Streamlined Manufacturing and Cost Efficiencies.** We are building an efficient and scalable manufacturing process and organization. The allogeneic approach utilizes healthy donor T cells which we believe provides enhanced scalability, reduces costs of engineered T cell therapy and reduces costs to the healthcare system as our allogeneic approach does not require us to collect and track T cells from each individual patient.



## Manufacturing Allogeneic T Cells

There are similarities as well as key differences between the processes for allogeneic and autologous T cell manufacturing, as illustrated in the figure below.



The three primary steps to creating our engineered allogeneic CAR T cells are: (1) collection and transduction, (2) gene editing, and (3) purification, formulation, and storage.

### Step 1. Collection and Transduction

The starting material for our allogeneic T cell products is white blood cells from a healthy donor, which are collected using a standard blood bank procedure known as leukapheresis. The collected cells are then screened, tested, and shipped to a central processing facility, where the T cells are isolated and stored frozen, creating an inventory of starting healthy donor cells for manufacturing.

The manufacturing process starts by thawing frozen healthy donor T cells, which are then stimulated to proliferate and transduced with a viral vector to integrate the CAR sequence into the T cell genome. The CAR sequence directs the expression of CAR proteins on the cell surface that allows the transduced T cells to recognize and bind to a target molecule that is present on cancer cells.

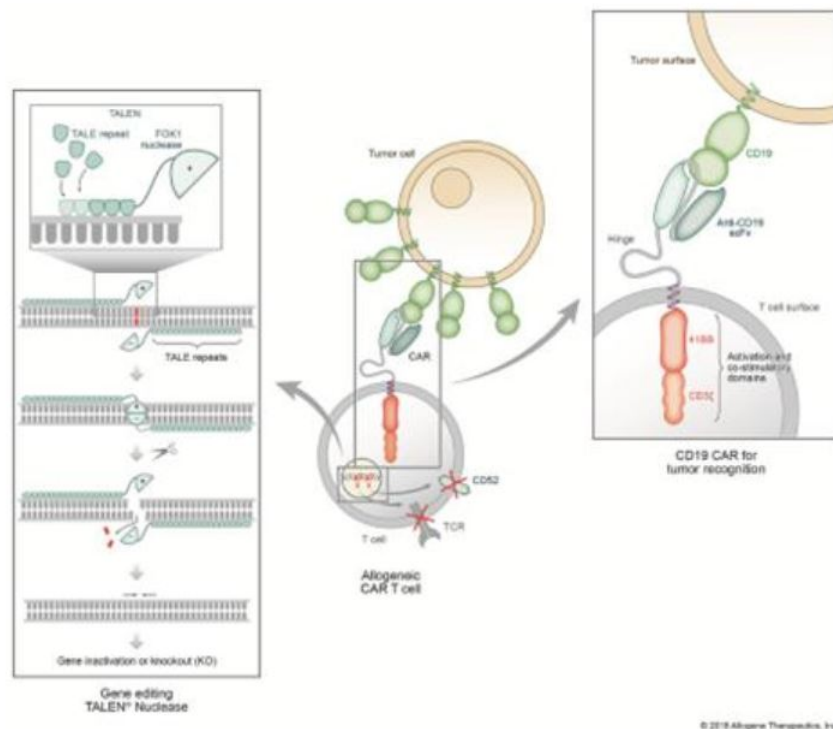
We can concurrently add additional genes to these cells that confer specific properties. For example, we can add an off-switch by expressing proteins that can make T cells susceptible to certain drugs, such as anti-CD20 monoclonal antibodies, and enable us to deplete our engineered T cells if needed by administering such drugs to the patient. We can also introduce cytokine activation signaling within a CAR T cell that is designed to enhance the proliferative potential, migratory behavior, and killing activity of cells. We are investigating multiple constructs designed to mimic cytokine signaling selectively within CAR T cells, a technology platform that we call “TurboCARs”.

### Step 2. Gene Editing

Next, we use Collectis’s electroporation and TALEN technologies for gene editing of T cells. TALENs are a class of DNA cutting enzymes derived by fusing the DNA-cutting domain of a nuclease to the DNA-binding domains from transcription activator-like effectors (TALE). The TALE DNA-binding domain can be tailored to specifically recognize a unique DNA sequence. These fusion proteins serve as readily targetable “DNA scissors” for genome engineering applications that enable us to perform targeted genome modifications such as sequence insertion, deletion, repair and replacement in living cells.

Electroporation allows TALEN mRNA to enter into the cell, where it is translated into a nuclease that can cut DNA and inactivate specific target genes. Inactivation of genes, such as TCR $\alpha$  and CD52, which is performed for UCART19, ALLO-501, ALLO-501A, and ALLO-715, is intended to reduce the risk of GvHD and allow the allogeneic T cells to expand and persist in patients. We believe the inactivation of other target genes using the TALEN technology can be incorporated into future product candidates, with the goal of enhancing T cell function, including increasing potency against solid tumors.

The figure below illustrates how we utilize Collectis’s TALEN and electroporation technology to inactivate the genes coding for TCR $\alpha$  and CD52 in our allogeneic T cells for UCART19.

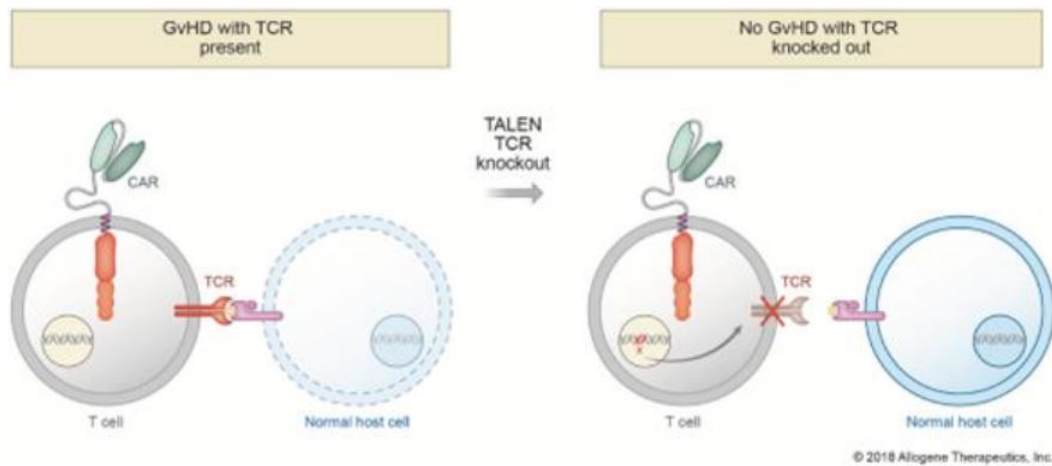


We believe the key benefits of TALEN technology are:

- **Precision.** It is possible to design a TALEN that will cleave at any selected region in any gene, giving us the ability to achieve the desired genetic outcome with any gene.
- **Specificity and Selectivity.** TALEN may be designed to limit its DNA cleavage to the desired sequence and to reduce the risk of cutting elsewhere in the genome. This parameter is essential, especially for therapeutic applications, because unwanted genomic modifications potentially could lead to harmful effects for the patient. In addition, gene editing requires only a transient presence of TALEN, thus preserving the integrity and functionality of the T cell’s genome.
- **Efficiency.** A large percentage of cells treated by the nuclease bear the desired genomic modification after treatment is completed. We believe the efficiency of TALEN editing helps to improve our manufacturing yields.

**TCR $\alpha$  knockout:** Non-modified allogeneic T cells bear functional TCRs and, if injected into a patient, can potentially recognize the patient’s tissue as foreign and damage it. This reaction, known as GvHD, is mediated by intact TCRs on allogeneic T cells. To reduce the risk of GvHD, all of our product candidates undergo the inactivation of a gene coding for

TCR $\alpha$ , a key component of TCRs. The engineered T cells lacking functional TCRs are no longer capable of recognizing peptide antigens presented on major histocompatibility complex proteins and thus incapable of attacking the patient's normal tissue. This could mitigate the risk of GvHD that can occur when allogeneic TCR-positive T cells are infused into patients who are unrelated to the healthy donor, as shown in the figure below.



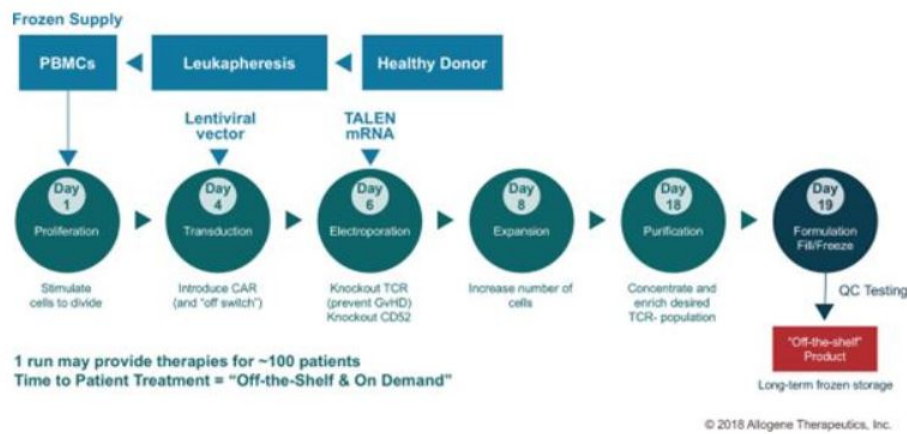
*CD52 knockout:* The patient's immune system is expected to recognize allogeneic T cells as foreign and destroy or reject them. To delay this rejection, we use anti-CD52 antibody to deplete lymphocytes, including T cells, in patients. Anti-CD52 antibody recognizes CD52 protein expressed on many immune cells, including T cells. CD52 protein is expressed in both donor and patient immune cells. To selectively deplete a patient's immune cells while sparing the therapeutic allogeneic T cells, we use TALEN gene editing to inactivate the CD52 gene in allogeneic T cells, thus protecting allogeneic T cells from the anti-CD52 antibody mediated depletion.

By administering anti-CD52 antibody prior to infusing our product candidates, we believe we can reduce the likelihood of a patient's immune system rejecting the engineered allogeneic T cells for a sufficient period of time to enable a window of persistence during which our engineered allogeneic T cells can expand and actively target and destroy cancer cells. We also believe our approach is unique and differentiated. To capitalize on this differentiation and to secure our own source of anti-CD52 monoclonal antibody, we are developing ALLO-647. We are currently utilizing ALLO-647 in the ALPHA trial and UNIVERSAL trial, and plan to utilize ALLO-647 in the ALPHA2 trial.

### Step 3. Purification, Formulation, and Storage

Once the allogeneic T cells have been engineered with CARs and gene edited to remove the genes encoding TCR $\alpha$  and CD52, they are cultured for several days to increase the cell number and then harvested. The allogeneic cells then undergo a purification step to remove residual TCR positive cells that have not undergone TCR $\alpha$  gene editing. We believe this purification step is essential as none of the currently available gene-editing nucleases can completely inactivate the target genes. After overnight recovery, the cells are formulated in a cryopreservation media and filled into closed, stoppered vials prior to controlled-rate freezing and long-term storage in the vapor phase of liquid nitrogen. This inventory is securely stored and then shipped to oncology centers as needed.

The figure below illustrates the steps in a manufacturing run for our engineered allogeneic CAR T product candidates.



## Product Pipeline and Development Strategy

Using our proprietary allogeneic T cell platform, we are researching and developing multiple product candidates for the treatment of blood cancers and solid tumors. Our product candidates are allogeneic T cells engineered to be used as off-the-shelf treatments for any patient with a particular cancer type. Each product candidate targets a selected antigen expressed on tumor cells and bears specific engineered attributes.

In the near term, we are progressing multiple product candidates directed at promising targets for blood cancers, including ALL, NHL, multiple myeloma and AML. We are also conducting earlier-stage research programs focused on targets associated with solid tumors, such as renal cell carcinoma, small cell lung cancer and other common epithelial cancers.

Our product pipeline is represented in the diagram below:

CATEGORY	PROGRAM	PRE-CLINICAL	PHASE 1	PHASE 2/3 <sup>1</sup>	
Hematological Malignancies	CD19	UCART19 (ALL) <sup>2</sup>	██████████		
		ALLO-501 (NHL) <sup>2 3</sup>	██████████		
		ALLO-501A (NHL) <sup>2 3</sup>	██████████		
	BCMA	ALLO-715 (MM)	██████████		
		ALLO-715 + nirogacestat (MM) <sup>5</sup>	██████████		
		ALLO-605 (TurboCAR™/MM)	██████████		
		ALLO-316 (CD70)	██████████		
Solid Tumors	ALLO-819 (FLT3/AML)	██████████			
	ALLO-316 (CD70/RCC)	██████████			
	DLL3 (SCLC)	██████████			
Lymphodepletion Agent	Multiple Undisclosed Targets	██████████			
		ALLO-647 (Anti-CD52 mAb) <sup>4</sup>	██████████		

<sup>1</sup> Phase 3 may not be required if Phase 2 is registrational.

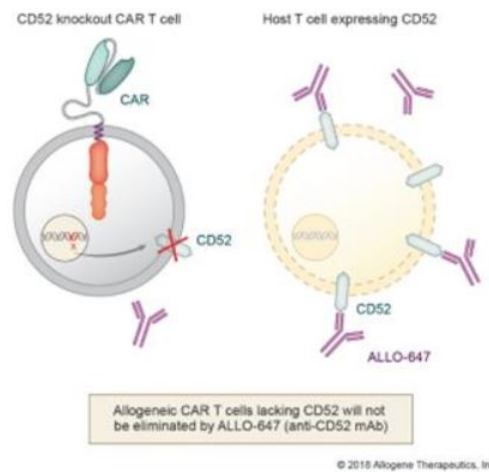
<sup>2</sup> Servier will hold ex-US commercial rights. Servier is the sponsor of the UCART19 trials.

<sup>3</sup> Allogene is the sponsor of the ALLO-501 trial and plans to sponsor a trial for ALLO-501A.

<sup>4</sup> ALLO-647 intended to enable expansion and persistence of allogeneic CAR T product candidates.

<sup>5</sup> *Allogene sponsored trial in combination with SpringWorks Therapeutics, Inc.*

In addition to the allogeneic CAR T cell product candidates we are developing for the treatment of blood cancers and solid tumors, we are developing an anti-CD52 monoclonal antibody, ALLO-647, which is designed to be used prior to infusing our other product candidates as part of the lymphodepletion regimen. As illustrated below, we believe ALLO-647 can reduce the likelihood of a patient's immune system from rejecting the engineered allogeneic T cells for a sufficient period of time to enable a window of persistence during which our engineered allogeneic T cells can actively target and destroy cancer cells.



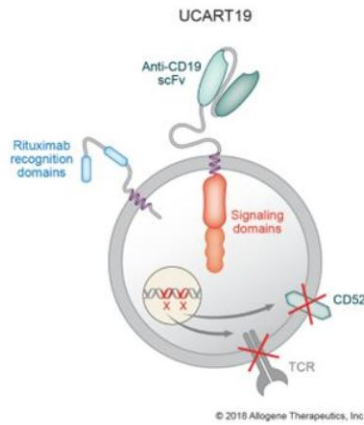
## UCART19

We, in partnership with Servier, are developing UCART19 to be a potential first-in-class allogeneic CAR T cell product candidate for the treatment of pediatric and adult patients with R/R CD19 positive B-cell ALL. There are currently two ongoing Phase 1 clinical trials in adult and pediatric R/R ALL. Servier is the sponsor of the UCART19 clinical trials and is also responsible for manufacturing UCART19.

UCART19 targets CD19, an antigen expressed on the surface of B cells, including malignant B cells. In addition to these indications, CD19 targeting CAR T therapies have shown preliminary efficacy in chronic lymphocytic leukemia, mantle cell lymphoma and low-grade NHLs, such as FL or marginal zone lymphoma.

UCART19 is manufactured to express a CAR that is designed to target CD19 and gene edited to lack TCR $\alpha$  and CD52 to minimize the risk of GvHD and enable a window of persistence in the patient. In addition, UCART19 cells are engineered to express a small protein on the cell surface called RQR8, which consists of two rituximab recognition domains. This allows for recognition and elimination of cells in the event that silencing of CAR T cell activity is desired. The figure below depicts the construct of UCART19.





### **Target Indication: Acute Lymphoblastic Leukemia (ALL)**

ALL is characterized by the proliferation of immature lymphocytes in the bone marrow. Approximately 6,150 new cases and 1,520 deaths in the United States are estimated in 2020, according to the American Cancer Society. Approximately 80% of cases of ALL are B-cell ALL, which we plan to address with UCART19.

The risk for developing ALL is highest in children younger than five years of age. From age five until the mid-20s, the risk declines slowly and begins to steadily rise again after age 50. Overall, about 40% of all cases of ALL are in adults. Though most cases occur in children, approximately 80% of deaths from ALL occur in adults.

Over the past four decades pediatric cure rates have reached greater than 80% in developed countries. This progress can be attributed, in part, to a deeper understanding of the molecular genetics and pathogenesis of the disease, advances in combination chemotherapy, monitoring of minimal residual disease, and use of tyrosine kinase inhibitors for Philadelphia chromosome–positive ALL. Allogeneic stem-cell transplant (allo-SCT) offers the potential for cure in some individuals, however, the option is available only to approximately a third of patients due to the lack of compatible stem cell source, general health, or the high risk of complications. Furthermore, allo-SCT carries a high rate of treatment-related mortality which can occur in approximately 20-30% of patients undergoing allo-SCT. In patients with R/R ALL after two or more lines of therapy, the median disease-free survival is less than six months. The five-year overall survival in adults over the age of 60 is approximately 20%, highlighting the high unmet need despite the recent advances in the treatment of ALL.

### **Clinical Data**

UCART19 is being studied in two ongoing Phase 1 clinical trials, CALM and PALL, sponsored and conducted by Servier, our collaboration partner. Initiated in 2016, CALM is an ongoing Phase 1, open-label, dose-escalation clinical trial in adult patients with R/R ALL to evaluate safety, anti-leukemic activity, and determine the maximum tolerated dose. Post-therapy allo-SCT was allowed at the discretion of the investigator. Initiated in 2016, PALL is an ongoing Phase 1, open-label, clinical trial in pediatric R/R ALL patients to evaluate safety and anti-leukemic activity.

Prior to the initiation of CALM and PALL, UCART19 was administered to three patients with CD19 positive B-cell ALL (two children and one adult) under a compassionate use license granted by the Medicines and Healthcare Products Regulatory Agency in the United Kingdom. The patients had previously failed multiple lines of prior treatment. UCART19 for these patients was manufactured at an academic site, the University College London. The two pediatric patients achieved a CR and received allo-SCT, and the one adult died within the first month following UCART19 infusion due to disease progression.

### **Pooled CALM and PALL Interim Clinical Findings**

In December 2018, interim results from 21 patients in the CALM and PALL clinical trials were presented at the 60th ASH Annual Meeting. As of the October 23, 2018 data cutoff, 21 patients enrolled had been treated in the CALM and PALL clinical trials. In the CALM trial, six patients were treated at the first dose level of  $6 \times 10^6$  total cells (approximately  $10^5$  cells per kilogram) and six patients were treated at the second dose level with  $8 \times 10^7$  total cells (approximately  $10^6$  cells per kilogram). Two patients were treated at the third dose level of  $1.8$  to  $2.4 \times 10^8$  total cells. In the PALL trial, all seven of the patients enrolled had been treated at a weight-banded cell dose equivalent to  $1.1$  to  $2.3 \times 10^6$  cells/kg. Patient characteristics are presented below.

	All (N=21)
<b>Median age in yrs (range)</b>	22 (0.8-62)
<b>No of prior treatment lines</b>	
1 to 3	7
≥4	14
Median (range)	4 (1-6)
<b>Previous allo-SCT</b>	13
<b>Time of relapse following previous allo-SCT</b>	
< 6 months	4
≥ 6 months	9
<b>Bone marrow blasts prior to lymphodepletion</b>	
<5%	6
5-25%	6
>25%	9
Median (range)	8% (0-96)

*Interim Safety*

The table below summarizes the adverse events by grade related to UCART19 infusion as well as those related to the lymphodepletion regimen as of October 23, 2018. Grade 1 represents mild toxicity, Grade 2 represents moderate toxicity, Grade 3 represents severe toxicity and Grade 4 represents life threatening toxicity. Grade 5 toxicity represents toxicity resulting in death.

N=21	Worst Grade					All Grades n(%)
	G1 n(%)	G2 n(%)	G3 n(%)	G4 n(%)	G5 n(%)	
<b>AEs related to UCART19</b>						
Cytokine release syndrome	4 (19.0)	12 (57.1)	2 (9.5)	1*(4.8)	—	19 (90.5)
Neurotoxicity events	7 (33.3)	1 (4.8)	—	—	—	8 (38.1)
Acute skin graft-versus-host disease(1)	2 (9.5)	—	—	—	—	2 (9.5)
<b>AEs related to lymphodepletion and/or UCART19</b>						
Prolonged cytopenia(2)	—	—	—	6+ (28.5)	—	6 (28.5)
Viral infections(3)	1 (4.8)	2 (9.5)	4 (19.0)	1 (4.8)	—	8 (38.1)
Neutropenic sepsis	—	—	—	1 (4.8)	1* (4.8)	2 (9.5)
Febrile neutropenia / septic shock	—	—	—	—	1 (4.8)	1 (4.8)
Pulmonary hemorrhage	—	—	—	—	1+ (4.8)	1 (4.8)

(1) GvHD confirmed by biopsy in 1 out of 2 cases.

(2) Persistent Grade 4 neutropenia and/or thrombocytopenia beyond day 42 post UCART19 infusion, except if >5% bone marrow blast.

(3) Viral infections: CMV, ADV, BK virus, metapneumovirus.

\* One dose limiting toxicity at Dose Level 1: Grade 4 CRS associated with Grade 5 neutropenic sepsis (death at D15 post-infusion).

+ One dose limiting toxicity at Dose Level 2: Grade 4 prolonged cytopenia associated with infection and Grade 5 pulmonary hemorrhage (death at D82 post-infusion).

The most common UCART19 related adverse event was CRS, reported in 19 patients. Grade 3 or 4 CRS was observed in three patients. Six patients developed prolonged cytopenia, defined as persistent Grade 4 neutropenia and/or thrombocytopenia beyond day 42 after UCART19 infusion. Seven patients experienced mild, or Grade 1, neurotoxicity events and one patient experienced Grade 2 neurotoxicity events. Viral infections were attributed to lymphodepletion and/or UCART19. Two patients experienced Grade 1 GvHD adverse event of the skin, which resolved with steroids.

As previously presented, there were two treatment-related deaths in the CALM study, one at day 15 post infusion as a result of Grade 4 CRS associated with Grade 5 neutropenic sepsis and one at day 82 post infusion with Grade 5 pulmonary hemorrhage in the post allogeneic stem-cell transplant setting. Since the data cut-off, one additional CALM patient was treated

at the third dose level and died of a treatment-related multiple organ dysfunction syndrome. Grade 5 adverse events have been reported in other autologous anti-CD19 CAR T cell therapy trials in part due to advanced stage of disease and accompanying confounding conditions.

Of the 21 evaluable patients, thirteen deaths have been reported that were not attributed to UCART19, but due to progressive disease or allo-SCT related complications.

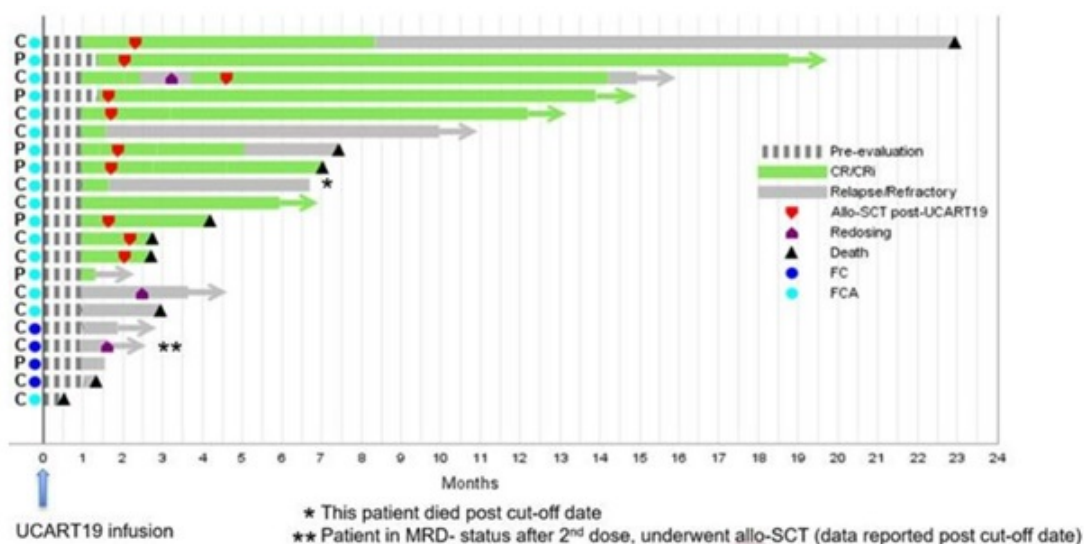
*Interim Efficacy*

As of October 2018, 67% (14/21) of patients achieved a CR/CRi. Eighty-two percent (14/17) of patients who received a lymphodepletion regimen consisting of fludarabine, cyclophosphamide and an anti-CD52 monoclonal antibody (FCA) achieved a CR/CRi. In the four patients who received fludarabine and cyclophosphamide (FC) only, there was no evidence of UCART19 cell expansion and no response. Seventy-one percent (10/14) of patients achieved MRD- CR. Three patients received a second dose of UCART19, two under compassionate use (as a deviation from the clinical trial protocol) and one under amended protocol, and two achieved cell expansion and MRD- CR. MRD- CR occurs when a patient achieves a CR and there is no evidence of ALL cells in the marrow when using sensitive tests such as polymerase chain reaction or flow cytometry. CR or CRi rates are the typical regulatory standard, but studies in both children and adults with ALL have demonstrated a strong correlation between minimal residual disease (MRD+) and risks for relapse.

We believe these data suggest an anti-CD52 antibody is an important addition to the lymphodepletion regimen for allogeneic CAR T cell expansion. We therefore believe that an anti-CD52 antibody is important to the success of our allogeneic CAR T platform. Going forward, the PALL and CALM trials will require the use of an anti-CD52 monoclonal antibody in the lymphodepletion regimen.

CAR T cell expansion was detected in blood from day 7 after UCART19 infusion, reaching the peak expansion between day 10 and day 17. One patient treated in the CALM trial at the second dose level showed the highest peak linked to a long persistence up to 4 months.

The four patients on the FC regimen showed no evidence of CAR T cell expansion. A similar lack of CAR T cell expansion was seen in two out of 10 patients on the FCA regimen. The following table illustrates response, duration of remission and re-dosing of UCART19 in the CALM and PALL trial as of the October 2018 data cutoff.



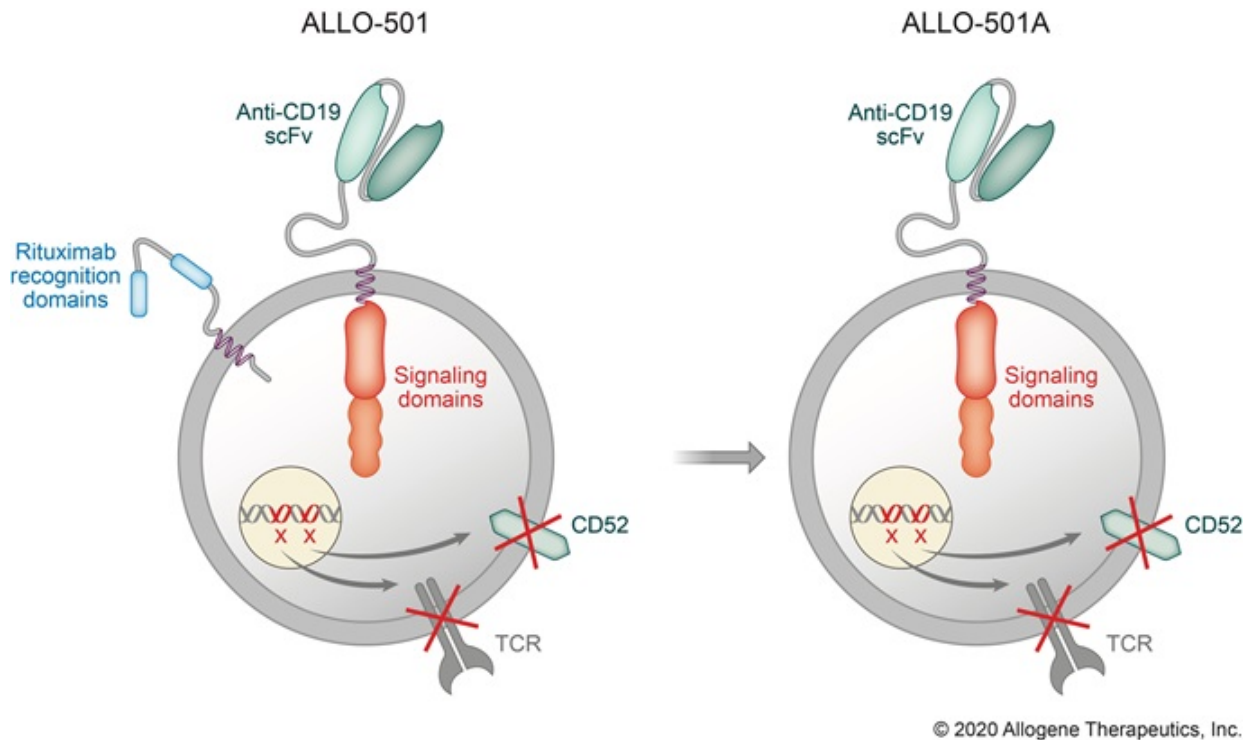
**Development Plan**

We, in partnership with Servier, plan to continue to advance UCART19 in CALM and PALL in order to determine the recommended Phase 2 dose level and the optimal lymphodepletion regimen, specifically testing the benefits of anti-CD52 monoclonal antibody, alemtuzumab or ALLO-647. Subject to the continued advancement of the Phase 1 trials, we expect UCART19 to be advanced to potential registrational trials, CALM2 and PALL2, in 2021.

## ALLO-501 and ALLO-501A

ALLO-501 and ALLO-501A are our other allogeneic CAR T cell product candidates targeting CD19. ALLO-501 is identical to UCART19 in molecular design, however several modifications have been introduced by us to the manufacturing process for ALLO-501. These modifications are designed to facilitate more efficient manufacturing scale-up for the larger patient population targeted by ALLO-501. Like UCART19, ALLO-501 also co-expresses a small protein on the cell surface called RQR8, which consists of two rituximab recognition domains. This allows for destruction of the CAR T by rituximab.

Prior treatment with rituximab is typical for patients with NHL and, depending on the lag time between the rituximab administration and planned ALLO-501 infusion, prior administration of rituximab may interfere with ALLO-501. As a result, we have removed RQR8 in the next generation of ALLO-501, known as ALLO-501A, as illustrated in the figure below. We believe ALLO-501A will have the potential to facilitate treatment of patients who were recently treated with rituximab. ALLO-501A has been manufactured from several donors under non-cGMP conditions and has been compared to the current version of ALLO-501 *in vitro*. In this study, we found that ALLO-501 and ALLO-501A exhibited similar characteristics and killing activity.



ALLO-501 and ALLO-501A are jointly developed by us and Servier. We are the sponsor of the ALLO-501 and ALLO-501A trials and lead the clinical development program.

### Target Indication: Non-Hodgkin Lymphoma (NHL)

NHL is a hematologic cancer originating from malignant lymphocytes. It is the most common hematological malignancy in the United States, with 77,240 new cases estimated to be diagnosed and 19,940 deaths estimated in 2020, according to the American Cancer Society. Over 60 NHL subtypes have been identified, and each subtype represents different neoplastic lymphoid cells (T, B or NK cells) that have arrested at different stages of differentiation. The most common subtype is B-cell, which represented over 90% of all new NHL cases in 2016.

B-cell NHL itself represents a group of different neoplasms that not only differ in pathology, but also response to therapy and prognosis. NHL can be rapidly growing (aggressive) with short survival, such as large B-cell lymphomas, which include diffuse large B cell lymphoma (DLBCL), or it can be slow growing, or indolent, such as FL. Despite recent therapeutic advances, more than 50% of patients with aggressive B-cell NHL are incurable using existing approved therapies.

The R-CHOP chemotherapy combination (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) introduced in the early 2000s remains the standard of care for newly diagnosed DLBCL, and five-year survival can be achieved for 55-60% of patients. Unfortunately, approximately 30% of DLBCL require second-line therapy, and subsequent therapy is dependent on whether the patients are candidates for high-dose therapy followed by autologous stem-cell therapy. A retrospective analysis of patients with R/R DLBCL, who were not treated with autologous CAR T therapy, found that outcomes in this population are poor, with an objective response rate of 26% (CR: 7%, partial response: 18%) and median overall survival of 6.3 months.

Despite availability of multiple active agents, high response rates, and long progression-free survival with first-line therapy, FL remains an incurable disease. Most patients treated today eventually relapse, and subsequent responses and durations of responses become increasingly shorter. Ultimately, patients become resistant to chemo-immunotherapy, clinically defined as relapsed within 12 months. In these patients, the toxicity commonly outweighs the benefit of treatment with chemotherapy. Therefore, there remains a high unmet medical need for newer treatment options, especially for those patients with cancer that is resistant to chemo-immunotherapy.

### **Clinical Development Plan**

The ALPHA trial is an open-label, Phase 1, single arm, multicenter clinical trial evaluating the safety and tolerability of ALLO-501 in adult patients with R/R large B-cell lymphoma, including DLBCL, or FL. Cell kinetics and pharmacodynamics of ALLO-501 will be evaluated as secondary and exploratory objectives, respectively. The trial is a dose-escalation study for ALLO-501 with three separate dose cohorts, from  $40 \times 10^6$  to  $360 \times 10^6$  total cells. Prior to ALLO-501 treatment, all patients undergo lymphodepletion with a regimen of fludarabine, cyclophosphamide and ALLO-647. We have recently completed enrollment of the three cell dose escalation cohorts, and we are currently exploring the optimal dose and schedule of ALLO-647 in additional cohorts as well as re-dosing of certain patients. We expect to report initial data from the ALPHA trial in the second quarter of 2020.

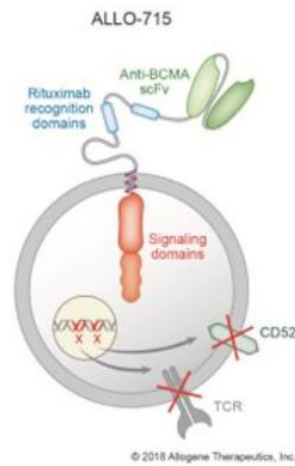
We plan to initiate an open-label, Phase 1/2, single arm, multicenter clinical trial (the ALPHA2 trial) evaluating the safety and efficacy of ALLO-501A in adult patients with R/R large B-cell lymphoma, including DLBCL, or transformed FL. Cell kinetics and pharmacodynamics of ALLO-501 will be evaluated as secondary and exploratory objectives, respectively. In December 2019, the FDA cleared our IND to initiate the ALPHA2 trial and we plan to initiate the trial in the second quarter of 2020, subject to completing the manufacturing of ALLO-501A. The Phase 1 portion of the ALPHA2 trial is designed to assess the safety and tolerability at increasing dose levels of ALLO-501A, and identify the recommended doses of ALLO-501A and ALLO-647 for use in the Phase 2 portion of the trial. We also expect certain patients to be eligible for re-treatment. We expect to dose approximately ten patients in the Phase 1 portion of the trial, subject to the results of the ALPHA trial and ALPHA2 trial including safety data.

All patients treated with ALLO-501 and ALLO-501A will be followed in a long-term follow-up study.

### **ALLO-715**

ALLO-715 is an allogeneic CAR T cell product candidate targeting BCMA. BCMA is a member of the tumor necrosis factor receptor family and is selectively expressed on immunoglobulin-producing plasma cells, including malignant plasma cells (myeloma cells). We initiated a Phase 1 clinical trial (the UNIVERSAL trial) of ALLO-715 in adult patients with R/R multiple myeloma in the third quarter of 2019.

ALLO-715 is manufactured to express a CAR that is designed to target BCMA and gene edited to lack TCR $\alpha$  and CD52 to minimize the risk of GvHD and enable a window of persistence in the patient. In addition, rituximab recognition domains, as an off-switch, has been incorporated in between the scFv and the linker domain. The figure below depicts the construct of ALLO-715.



**Target Indication: Multiple Myeloma**

Multiple myeloma is a hematological malignancy that is characterized by uncontrolled expansion of bone marrow plasma cells. There will be an estimated 32,270 new cases of multiple myeloma and 12,830 deaths from multiple myeloma in 2020 in the United States according to the American Cancer Society. Multiple myeloma predominantly affects the elderly, with 14 times more patients diagnosed at age 65 and over than those diagnosed under the age of 65.

For patients less than age of 70 with no comorbidities, autologous stem cell therapy is the preferred option to provide a durable response. For transplant ineligible patients, immunomodulatory drugs (Revlimid, Pomalyst, Thalomid) and proteasome inhibitors (Velcade, Kyrprolis, Ninlaro), often used in combination with one another, have displaced older cytotoxic agents as the mainstay of treatment. In the past five years, several new drugs with novel mechanisms (Darzalex, Emlipiciti, Farydak) have been approved for multiple myeloma, however none of these novel treatments is considered as curative.

Despite the introduction of newer therapies, a majority of patients are expected to relapse and the unmet need in patients with R/R myeloma remains high. In clinical trials, only 3% of patients who were previously treated with at least three lines of therapy (including proteasome inhibitors and immunomodulatory drugs), or who were refractory to both proteasome inhibitors and immunomodulatory drugs, achieved a complete response to Darzalex. Median survival in such patients was just 17.5 months. Trials of autologous CAR T cell therapies such as bb2121, currently being developed by bluebird bio, Inc. (bluebird) in partnership with Celgene Corporation, have shown significant promise in multiple myeloma with complete response rates of 31% at doses of  $150 \times 10^6$  to  $450 \times 10^6$  CAR T cells.

**Clinical Development Plan**

The UNIVERSAL trial is an open-label, Phase 1, single arm, multicenter clinical trial evaluating the safety and tolerability of ALLO-715 in adult patients with R/R multiple myeloma. The safety of ALLO-647, cell kinetics, pharmacodynamics, and efficacy will be evaluated as secondary objectives. The trial is a dose-escalation study for ALLO-715 with three initial planned dose cohorts, from  $40 \times 10^6$  to  $320 \times 10^6$  total cells. Prior to ALLO-715 treatment, patients undergo lymphodepletion with a regimen of fludarabine, cyclophosphamide and ALLO-647. Up to 24 patients are expected to be enrolled in the dose finding stage of the trial. We also expect to explore different lymphodepletion regimens where the chemotherapy components, specifically fludarabine and cyclophosphamide, will be stepwise removed, and we will also explore the optimal dosing and schedule of ALLO-647. Additional patients may also be enrolled for further dose expansion.

We expect to report initial data from the trial in the fourth quarter of 2020. In addition, in January 2020, we entered into a clinical trial collaboration agreement with SpringWorks to evaluate ALLO-715 in combination with SpringWorks' investigational gamma secretase inhibitor (GSI), nirogacestat, in patients with R/R multiple myeloma. We plan to initiate this combination trial in the second half of 2020, subject to regulatory clearance.

## Future Opportunities

Moving forward, we plan to utilize our allogeneic platform to pursue additional targets of interest. These include the additional targets currently in our pipeline as well as other targets that might be validated in the future. For example, we are developing allogeneic CAR T cell product candidates targeting CD70 for the treatment of hematologic malignancies and renal cell carcinoma (ALLO-316), FLT3 for the treatment of AML (ALLO-819), and DLL3 for the treatment of small cell lung cancer (SCLC).

- **Renal Cell Carcinoma and ALLO-316.** Analysis using proteomic and immunohistochemistry techniques have demonstrated a high level of CD70 expression in clear cell renal cell carcinoma (ccRCC) cell lines and in more than 80% of human ccRCC tumor samples. ccRCC is the most common subtype of renal cancer. Approximately 73,750 new cases of renal cell carcinoma are estimated to be diagnosed in the United States and 14,830 deaths are estimated in 2020, according to the American Cancer Society. While the median survival for patients with stage IV disease was a little over one year when cytokines were the predominant systemic therapies, analyses from the International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) based upon more than 2,200 patients treated with targeted therapies report a median survival of 28 months in patients who were eligible for clinical trials. Another contemporary trial using targeted therapy reported a median survival of 28 to 29 months in patients treated with sunitinib or pazopanib, mirroring the IMDC results. We have selected an anti-CD70 CAR T candidate, ALLO-316, and are progressing IND-enabling studies, with the goal of submitting an IND by year-end 2020.
- **Acute Myeloid Leukemia and ALLO-316 and ALLO-819.** AML is a high unmet medical need with few treatment options. It is a cancer of bone marrow stem cells and is the most common type of leukemia in adults. The American Cancer Society estimates 19,940 new diagnoses and 11,180 deaths in the United States in 2020. Patients have a poor prognosis despite improvements in chemotherapy regimens and supportive care. CD70 is expressed on AML bulk cells and leukemic stem cells and we expect our planned clinical trial of ALLO-316 to allow for the treatment of patients with AML. In addition, FLT3 is a receptor tyrosine kinase that is overactive in AML blasts. We have conducted *in vitro* and *in vivo* studies of our anti-FLT3 CAR T candidate, ALLO-819, that show anti-tumor activity against blasts present in bone marrow from AML patients and in mice. We are currently advancing an IND-enabling data set for ALLO-819.
- **Small Cell Lung Cancer and DLL3.** DLL3 is a target which is being pursued for SCLC using ADCs, bi-specifics and autologous CAR T therapies. According to the American Cancer Society, approximately 228,820 new cases of lung cancer are expected to be diagnosed in the United States in 2020 and SCLC comprises approximately 10-15% of all lung cancers. SCLC is responsive to chemotherapy, but recurrence arises rapidly, with less than 7% of patients surviving over five years. SCLC has shown to be responsive to immunotherapy with approximately one-third of patients responding to PD-1/PD-L1 therapy and achieving a median overall survival of approximately thirteen months for patients who received PD-L1 and platinum-based chemotherapy. We believe an allogeneic anti-DLL3 CAR T cell product candidate could be used alone or in combination with PD-1/PD-L1 therapy. We are currently testing and refining constructs for an anti-DLL3 CAR T candidate, and following completion we plan to progress to IND-enabling studies.

We also plan to enhance our platform using next-generation technologies such as TurboCARs, switch technologies, including small-molecule induced off-switch, site-specific integration and multi-specific CARs.

- **TurboCARs and ALLO-605.** Mimicking cytokine activation signaling within a CAR T cell could enhance the proliferative potential, migratory behavior, and killing activity of cells. Such modulation may enhance the anti-tumor activity and durability of CAR T cells without affecting non-engineered immune cells. We are investigating multiple constructs designed to mimic cytokine signaling selectively within CAR T cells, a technology platform that we call “TurboCARs”. We are progressing our first TurboCAR, ALLO-605, which targets BCMA and uses a constitutive cytokine signaling domain and a rituximab-mediated off-switch, with the goal of submitting an IND in 2021.
- **Renewable Cell Source.** In November 2019, we entered into a Collaboration and License Agreement with Notch (the Notch Collaboration Agreement), pursuant to which Notch has granted to us an exclusive, worldwide, royalty-bearing, license to certain Notch intellectual property to develop and commercialize gene-edited T cell and/or natural killer cell products from iPSCs directed at certain CAR targets for initial application in NHL, ALL and multiple myeloma. We believe iPSCs may provide renewable starting material for our allogeneic CAR T cell product candidates that could allow for improved efficiency of gene editing, greater scalability of supply, product homogeneity and more streamlined manufacturing. We commenced the research collaboration with Notch in late 2019.

- **Site-Specific Integration.** Using a combination of gene-editing technology and homologous recombination technology we can potentially integrate the CAR expressing DNA into specific target genes within the T cell DNA. Such site-specific integration may allow the CAR or other transgenes to be introduced into T cells in a more homogeneous manner, allowing a more uniform and controlled expression of the proteins, with the goal of generating CAR T cell products that behave in a more consistent and predictable manner.
- **Multi-specific CARs.** We are investigating the utility of a single cell product targeting multiple antigens. This may be accomplished by including two antigen binding domains with different specificity in a single polypeptide encoding the CAR or in two separate polypeptides each encoding a CAR with different antigen specificity.

In addition, we continually survey the scientific and industry landscape for opportunities to license, partner or acquire technologies that may help us advance current or new T cell therapies for the benefit of patients.

## **Our Manufacturing Strategy**

We have invested resources to optimize our manufacturing process, including the development of improved analytical methods. We plan to continue to invest in process science, product characterization and manufacturing to continuously improve our production and supply chain capabilities over time.

Our product candidates are designed and manufactured via a platform comprised of defined unit operations and technologies. The process is gradually developed from small to larger scales, incorporating compliant procedures to create cGMP conditions. Although we have a platform-based manufacturing model, each product is unique and for each new product candidate, a developmental phase is necessary to individually customize each engineering step and to create a robust procedure that can later be implemented in a cGMP environment to ensure the production of clinical batches. This work is performed in our research and development environment to evaluate and assess variability in each step of the process in order to define the most reliable production conditions.

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. ALLO-501 is identical in molecular design to UCART19, but is produced using a modified manufacturing process, optimized by us. ALLO-501, ALLO-501A and ALLO-715 are manufactured in the United States by a CMO, and we will manage all other aspects of the supply, including planning, CMO oversight, disposition and distribution logistics.

The CMO that is manufacturing the clinical supply of ALLO-501, ALLO-501A and ALLO-715 is subject to cGMP requirements, using qualified equipment and materials. We also utilize separate third party contractors to manufacture cGMP raw materials that are used for the manufacturing of our product candidates, such as viral vectors that are used to deliver the applicable CAR gene into the T cells. We believe all materials and components utilized in the production of the cell line, viral vector and final T cell product are available from qualified suppliers and suitable for pivotal process development in readiness for registration and commercialization.

In addition, in February 2019, we entered into a lease for approximately 118,000 square feet to develop a state-of-the-art cell therapy manufacturing facility in Newark, California. We plan to phase the build-out of the facility, and expect to complete the build-out of the majority of the facility in the second half of 2020 and initiate cGMP manufacturing operations in 2021. However, we expect to continue to rely on our CMO and may rely on CMOs and other third parties for the manufacturing and processing of our product candidates in the future. We believe the use of contract manufacturing and testing for our first clinical product candidates has allowed us to rapidly prepare for clinical trials in accordance with our development plans. We expect third-party manufacturers will be capable of providing and processing sufficient quantities of our product candidates to meet anticipated clinical trial demands. We also utilize a CMO in the United States for the manufacture and supply of ALLO-647.

We plan to create a robust supply chain with redundant sources of supply comprised of both internal and external infrastructure.

## **Strategic Agreements**

We have also entered into multiple additional strategic agreements and collaborations, including an Asset Contribution Agreement with Pfizer (the Pfizer Agreement), a License Agreement with Cellectis (the Cellectis Agreement), an Exclusive License and Collaboration Agreement with Servier (the Servier Agreement) and the Notch Collaboration Agreement.



For additional information regarding our significant agreements, see Note 7 to our financial statements appearing elsewhere in this Annual Report.

## Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, as well as novel discoveries, product development technologies, and know-how. Our commercial success also depends in part on our ability to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Our policy is to develop and maintain protection of our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and applications related to our technology, inventions, and improvements that are important to the development and implementation of our business.

We also rely on trademarks, trade secrets, know-how, continuing technological innovation, confidentiality agreements, and invention assignment agreements to develop and maintain our proprietary position. The confidentiality agreements are designed to protect our proprietary information and the invention assignment agreements are designed to grant us ownership of technologies that are developed for us by our employees, consultants, or other third parties. We seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in our agreements and security measures, either may be breached, and we may not have adequate remedies. In addition, our trade secrets may otherwise become known or independently discovered by competitors.

With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of using and manufacturing the same.

We are actively building our intellectual property portfolio around our product candidates and our discovery programs, based on our own intellectual property as well as licensed intellectual property. Following the execution of the Pfizer Agreement, we are the owners of, co-owners of, or the licensee of multiple patents and patent applications in the United States and worldwide. These licensed assets include rights to the Collectis TALEN gene-editing technology to engineer T cells that lack functional TCRs and to inactivate the CD52 gene in donor cells. We have exclusive worldwide rights to these patents for certain antigen targets, including BCMA, and have U.S. rights to these patents for CD19. Our patent rights are composed of patents and pending patent applications that are solely owned by us, co-owned with Servier, co-owned with Collectis, exclusively licensed from Pfizer, exclusively licensed from Servier, or exclusively licensed from Collectis.

Our patent portfolio includes protection for our lead product candidates, UCART19, ALLO-501, ALLO-501A and ALLO-715, as well as our other research-stage candidates. With respect to UCART19, ALLO-501 and ALLO-501A, we have an exclusive license from Servier in the United States to patent rights covering composition of matter and methods of making and use covering UCART19, ALLO-501 and ALLO-501A. With respect to ALLO-715, we have an exclusive license from Pfizer to patent rights covering ALLO-715 in the United States and in foreign jurisdictions. These rights include composition of matter protection for ALLO-715 and methods of making and using ALLO-715. More generally, our patent portfolio and filing strategy is designed to provide multiple layers of protection by pursuing claims directed toward: (1) antigen binding domains directed to the targets of our product candidates; (2) CAR constructs used in our product candidates; (3) methods of treatment for therapeutic indications; (4) manufacturing processes, preconditioning methods, and dosing regimens; and (5) reducing GvHD, and methods for genetically engineering immune cells suitable for allogeneic use.

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, the patent term is 20 years from the date of filing of the first non-provisional application to which priority is claimed. In the United States, patent term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent. In the United States, the term of a patent that covers an FDA-approved drug may also be eligible for a patent term extension of up to five years under the Hatch-Waxman Act, which is designed to compensate for the patent term lost during the FDA regulatory review process. The length of the patent term extension involves a complex calculation based on the length of time it takes for regulatory review. A patent term extension under the Hatch-Waxman Act cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only one patent applicable to an approved drug may be extended. Moreover, a patent can only be extended once, and thus, if a single patent is applicable to multiple products, it can only be extended based on one product. Similar provisions are available in Europe and certain other foreign jurisdictions to extend the term of a patent that covers an approved drug.

## Competition

If successfully developed, our products will compete with novel therapies developed by biopharmaceutical companies, academic research institutions, governmental agencies and public and private research institutions, in addition to standard of care treatments.

Novartis and Kite were the first to achieve FDA approval for autologous T cell therapies. In August 2017, Novartis obtained FDA approval to commercialize Kymriah, the treatment of children and young adults with B-cell ALL that is refractory or has relapsed at least twice. In May 2018, Kymriah received FDA approval for adults with R/R large B-cell lymphoma. In October 2017, Kite obtained FDA approval to commercialize Yescarta, the first CAR T cell product candidate for the treatment of adult patients with R/R large B-cell lymphoma.

Due to the promising therapeutic effect of T cell therapies in clinical trials, we anticipate increasing competition from existing and new companies developing these therapies, as well as in the development of allogeneic T cell therapies. Potential cell therapy competitors include, but are not limited to:

- *Allogeneic T cell therapy competition:* Atara Biotherapeutics, Inc., Celyad S.A., CRISPR Therapeutics AG, Editas Medicine, Inc., Fate Therapeutics Inc., Gilead Sciences, Inc. (acquired Kite), Intellia Therapeutics, Inc., Poseida Therapeutics, Inc., and Precision Biosciences, Inc. Additionally, Cellectis has several fully-owned allogeneic CAR programs that could compete with programs that fall outside our agreement with Cellectis.
- *Autologous T cell therapy competition:* Adaptimmune Therapeutics PLC, Autolus Therapeutics plc, bluebird bio, Inc., Bristol-Myers Squibb Company, Gilead Sciences, Inc., Johnson & Johnson, Iovance Biotherapeutics, Inc., Mustang Bio, Inc., Novartis International AG, TCR<sup>2</sup> Therapeutics Inc., Tmunity Therapeutics, Inc., and Unum Therapeutics Inc.

Competition may also arise from non-cell based immune oncology platforms. For instance, we may experience competition from companies, such as Amgen Inc., Bristol-Myers Squibb Company, F. Hoffmann-La Roche AG, Genmab A/S, GlaxoSmithKline plc, MacroGenics, Inc., Merus N.V., Regeneron Pharmaceuticals, Inc., and Xencor Inc., that are pursuing bispecific antibodies, which target both the cancer antigen and T cell receptor, thus bringing both cancer cells and T cells in close proximity to maximize the likelihood of an immune response to the cancer cells. Additionally, companies, such as Amgen Inc., Daiichi Sankyo Company, Limited, GlaxoSmithKline plc, ImmunoGen, Inc., Immunomedics, Inc., and Seattle Genetics, Inc., are pursuing antibody drug conjugates, which utilize the targeting ability of antibodies to deliver cell-killing agents directly to cancer cells.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, pre-clinical testing, clinical trials, manufacturing, and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety, convenience, and cost of manufacturing.

These competitors may also vie for a similar pool of qualified scientific and management talent, sites and patient populations for clinical trials, and investor capital, as well as for technologies complementary to, or necessary for, our programs.

## Government Regulation and Product Approval

As a biopharmaceutical company that operates in the United States, we are subject to extensive regulation. Our cell products will be regulated as biologics. With this classification, commercial production of our products will need to occur in registered facilities in compliance with cGMP for biologics. The FDA categorizes human cell- or tissue-based products as either minimally manipulated or more than minimally manipulated, and has determined that more than minimally manipulated products require clinical trials to demonstrate product safety and efficacy and the submission of a BLA for marketing authorization. Our products are considered more than minimally manipulated and will require evaluation in clinical trials and the submission and approval of a BLA before we can market them.

Government authorities in the United States (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of biopharmaceutical products such as those we are developing. Our product candidates must be approved by the FDA before they may be legally marketed in the United States and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries. Generally, our activities in other countries will be subject to regulation that is similar in nature and scope as that imposed in the United States, although there can be important differences. Additionally, some significant aspects of regulation in Europe are addressed in a centralized way, but country-specific regulation remains essential in many respects. The process for obtaining regulatory marketing approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

#### *U.S. Product Development Process*

In the United States, the FDA regulates pharmaceutical and biological products under the Federal Food, Drug and Cosmetic Act (FDCA), the Public Health Service Act (PHSA) and their implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. FDA sanctions could include, among other actions, refusal to approve pending applications, withdrawal of an approval, a clinical hold, warning letters, product recalls or withdrawals from the market, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us. The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to good laboratory practices (GLPs) and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- approval by an independent Institutional Review Board (IRB) or ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices (GCPs) and any additional requirements for the protection of human research patients and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantial evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with cGMP, to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity and, if applicable, the FDA's current good tissue practices (GTPs) for the use of human cellular and tissue products;
- potential FDA audit of the nonclinical study and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological product candidate, including our product candidates, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs. The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trials.

Clinical trials involve the administration of the biological product candidate to patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted

under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research patients provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Certain clinical trials involving human gene transfer research also must be overseen by an Institutional Biosafety Committee (IBC), a standing committee to provide peer review of the safety of research plans, procedures, personnel training and environmental risks of work involving recombinant DNA molecules. IBCs are typically assigned certain review responsibilities relating to the use of recombinant DNA molecules, including reviewing potential environmental risks, assessing containment levels, and evaluating the adequacy of facilities, personnel training, and compliance with the National Institutes of Health Guidelines. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The biological product is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- *Phase 2.* The biological product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk to benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up. During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA, and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human patients, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its data safety monitoring board may 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. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biological product has been associated with unexpected serious harm to patients.

Concurrently with clinical trials, companies usually complete additional studies and must also develop additional information about the physical characteristics of the biological product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHSA emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological product candidate does not undergo unacceptable deterioration over its shelf life.

*U.S. Review and Approval Processes*

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA submission must include results of product development, laboratory and animal studies, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. The testing and approval processes require substantial time and effort and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act (PDUFA), as amended, each BLA must be accompanied by a significant user fee. The FDA adjusts the PDUFA user fees on an annual basis. PDUFA also imposes an annual program fee for biological products. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 or 74 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent, and/or effective for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (REMS) is necessary to assure the safe use of the biological product. A REMS is a safety strategy to manage a known or potential serious risk associated with a medicine and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS. The FDA will not approve a BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. For immunotherapy products, the FDA also will not approve the product if the manufacturer is not in compliance with the GTPs, to the extent applicable. These are FDA regulations and guidance documents that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissue, and cellular and tissue based products (HCT/Ps), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that cell and tissue based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements. To assure cGMP, GTP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production, and quality control.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. If the agency decides not to approve the BLA in its present form, the FDA will issue a complete response letter that describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a risk management plan, or

otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

In addition, under the Pediatric Research Equity Act (PREA), a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

#### *Orphan Drug Designation*

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States, or more than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for this type of disease or condition will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. After the FDA grants orphan drug designation, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. The orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review or approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval 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 full BLA, to market the same biologic 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. Orphan drug exclusivity does not prevent FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. In addition, exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

#### *Expedited Development and Review Programs*

The FDA has a fast track program that is intended to expedite or facilitate the process for reviewing new products that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. Unique to a fast track product, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Any product, submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions may receive accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Regenerative Medicine Advanced Therapy (RMAT) designation was established by FDA in 2017 to facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. Once approved, when appropriate, the FDA can permit fulfillment of post-approval requirements under accelerated approval through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence such as electronic health records; through the collection of larger confirmatory datasets; or through post-approval monitoring of all patients treated with the therapy prior to approval.

Breakthrough therapy designation is also intended to expedite the development and review of products that treat serious or life-threatening conditions. The designation by FDA requires preliminary clinical evidence that a product candidate, alone or in combination with other drugs and biologics, demonstrates substantial improvement over currently available therapy on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review.

Fast Track designation, priority review, RMAT and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

#### *Post-Approval Requirements*

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, 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. Although a physician may prescribe a legally available product for an off-label use, if the physician deems such product to be appropriate in his/her professional medical judgment, a manufacturer may not market or promote off-label uses. However, it is permissible to share in certain circumstances truthful and not misleading information that is consistent with the product's approved labeling.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk

management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

#### *U.S. Marketing Exclusivity*

The Biologics Price Competition and Innovation Act (BPCIA) amended the PHSA to authorize the FDA to approve similar versions of innovative biologics, commonly known as biosimilars. A competitor seeking approval of a biosimilar must file an application to establish its molecule as highly similar to an approved innovator biologic, among other requirements. The BPCIA, however, bars the FDA from approving biosimilar applications for 12 years after an innovator biological product receives initial marketing approval. This 12-year period of data exclusivity may be extended by six months, for a total of 12.5 years, if the FDA requests that the innovator company conduct pediatric clinical investigations of the product.

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our U.S. patents, if granted, may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. The Hatch-Waxman Act permits a patent restoration term of up to five years, as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The U.S. Patent and Trademark Office, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

#### *Other U.S. Healthcare Laws and Compliance Requirements*

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (HHS) (e.g., the Office of Inspector General, the U.S. Department of Justice (DOJ), and individual U.S. Attorney offices within the DOJ, and state and local governments). For example, our business practices, including any of our research and future sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the patient data privacy and security provisions of the Health Insurance Portability and Accountability Act (HIPAA), transparency requirements, and similar state, local and foreign laws, each as amended.

The federal Anti-Kickback Statute 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 purchasing, leasing, ordering or arranging for the purchase, lease or order of any item, good, facility or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The federal Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and other individuals and entities on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the Affordable Care Act, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal



Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Rather, if “one purpose” of the remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. In addition, the Affordable Care Act codified case law that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to, among others, a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent.

The federal civil False Claims Act prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. For example, pharmaceutical and other healthcare companies have been, and continue to be, investigated or prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product and for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, imposes requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to business associates that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the Affordable Care Act, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) annually report information to CMS related to certain payments or other transfers of value made or distributed to physicians, as defined by such law, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, physicians and teaching hospitals and certain ownership and investment interests held by physicians and their immediate family members.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, 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 the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

#### *Coverage, Pricing and Reimbursement*

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to which third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the United States, third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, or also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. 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.

Different pricing and reimbursement schemes exist in other countries. In the EU, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, 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 the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the United States has increased and we expect will continue to increase the pressure on healthcare pricing. 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.

#### *Healthcare Reform*

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product candidates for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

For example, the Affordable Care Act has substantially changed healthcare financing and delivery by both governmental and private insurers. Among the Affordable Care Act provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- created an annual, nondeductible fee on any entity that manufactures or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs that began in 2011;
- increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively, and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price (AMP);
- created a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts, off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;
- extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and added new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;
- expanded of the entities eligible for discounts under the 340B Drug Discount Program;
- created a Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;
- expanded healthcare fraud and abuse laws, including the Anti-Kickback Statute and the Foreign Corrupt Practices Act (FCPA), created new government investigative powers, and enhanced penalties for noncompliance;
- created a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted, or injected;
- required reporting of certain financial arrangements with physicians and teaching hospitals;
- required annual reporting of certain information regarding drug samples that manufacturers and distributors provide to physicians;
- established a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending; and
- created a licensure framework for follow on biologic products.

There remain legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, the current U.S. President has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, commonly known as the "individual mandate", as part of the Tax Cuts and Jobs Act of 2017 (Tax Act). In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax.

The Bipartisan Budget Act of 2018 (BBA), among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

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 2029 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.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient 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 2020 contains further drug price control measures that could be enacted during the 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. Additionally, the U.S. President's administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization to become effective, Congress and the 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 anticipate that these and other healthcare reform efforts will continue to result in additional downward pressure on coverage and the price that we receive for any approved product, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. 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.

#### *The Foreign Corrupt Practices Act*

The FCPA prohibits any U.S. individual or business from paying, offering, or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations.

#### *Additional Regulation*

In addition to the foregoing, state and federal laws regarding environmental protection and hazardous substances, including the Occupational Safety and Health Act, the Resource Conservancy and Recovery Act and the Toxic Substances Control Act, affect our business. These and other laws govern our use, handling and disposal of various biological, chemical and radioactive substances used in, and wastes generated by, our operations. If our operations result in contamination of the environment or expose individuals to hazardous substances, we could be liable for damages and governmental fines. We believe that we are in material compliance with applicable environmental laws and that continued compliance therewith will not have a material adverse effect on our business. We cannot predict, however, how changes in these laws may affect our future operations.

### *Europe / Rest of World Government Regulation*

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the EU, for example, a clinical trial application must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and IRB, respectively. Once the clinical trial application is approved in accordance with a country's requirements, clinical trial development may proceed. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational drug or biological product under EU regulatory systems, we must submit an MAA. The application used to file the BLA in the United States is similar to that required in the EU, with the exception of, among other things, country-specific document requirements.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

### *European Union General Data Protection Regulation*

In addition to EU regulations related to the approval and commercialization of our products, we may be subject to the EU's General Data Protection Regulation (GDPR). The GDPR imposes stringent requirements for controllers and processors of personal data of persons in the EU, 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.

### *California Consumer Privacy Act*

California recently enacted legislation, effective January 1, 2020, that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act (CCPA), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provides such consumers new ways to opt-out of certain sales of personal information, and allows for a new cause of action for data breaches. As our business progresses, the CCPA may impact (possibly significantly) our business

activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

## Employees

As of February 24, 2020, we had 206 total employees and 205 full-time employees. Of our full-time employees, 65 hold Ph.D. or M.D. degrees, and 151 are engaged in research, development and technical operations. Substantially all of our employees are located in South San Francisco, California. Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

## Corporate Information

We were incorporated in Delaware in November 2017. Our principal executive offices are located at 210 East Grand Avenue, South San Francisco, California 94080, and our telephone number is (650) 457-2700. Our corporate website address is [www.allogene.com](http://www.allogene.com). Information contained on or accessible through our website is not a part of this report, and the inclusion of our website address in this report is an inactive textual reference only.

## 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 Annual Report. The occurrence of any of the following risks could harm our business, financial condition, results of operations and growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report and those we may make from time to time.*

#### 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 multiple 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. Several support services were provided by Pfizer through a Transition Services Agreement (TSA), including certain research and development and general and administrative services, which terminated in September 2019. 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. If we are unable to build and manage our support services in a timely manner, our operating and financial results could differ materially from our expectations, and our business could suffer.

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

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

We are a clinical-stage biopharmaceutical company and investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval and become commercially viable. We have only recently acquired rights to an allogeneic CAR T platform of primarily early-stage product candidates and have no products approved for commercial sale and have not generated any revenue from product sales to date, and we will continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not profitable and have incurred net losses in each period since our inception. For the year ended December 31, 2019, we reported a net loss of \$184.6 million. As of December 31, 2019, we had an accumulated deficit of \$396.1 million.

We expect to incur significant expenditures for the foreseeable future, and we expect these expenditures to increase as we continue our research and development of, and seek regulatory approvals for, product candidates based on our engineered allogeneic T cell platform, including UCART19, ALLO-501A and ALLO-715. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***Our engineered allogeneic T cell product candidates represent a novel approach to cancer treatment that creates significant challenges for us.***

We are developing a pipeline of allogeneic T cell product candidates that are engineered from healthy donor T cells to express CARs and are intended for use in any patient with certain cancers. Advancing these novel product candidates creates significant challenges for us, including:

- manufacturing our product candidates to our or regulatory specifications and in a timely manner to support our clinical trials, and, if approved, commercialization;
- sourcing clinical and, if approved, commercial supplies for the raw materials used to manufacture our product candidates;
- understanding and addressing variability in the quality of a donor's T cells, which could ultimately affect our ability to produce product in a reliable and consistent manner and treat certain patients;
- educating medical personnel regarding the potential side effect profile of our product candidates, if approved, such as the potential adverse side effects related to cytokine release syndrome (CRS), neurotoxicity, graft-versus-host disease (GvHD), prolonged cytopenia and neutropenic sepsis;
- using medicines to manage adverse side effects of our product candidates which may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment;
- conditioning patients with chemotherapy and ALLO-647 or other lymphodepletion agents in advance of administering our product candidates, which may increase the risk of adverse side effects;
- obtaining regulatory approval, as the U.S. Food and Drug Administration (FDA) and other regulatory authorities have limited experience with development of allogeneic T cell therapies for cancer; and
- establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy.

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

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. For instance, gene-editing may create unintended changes to the DNA such as a non-target site gene-editing, a large deletion, or a DNA translocation, any of which could lead to oncogenesis. The gene-editing of our product candidates may also not be successful in limiting the risk of GvHD or premature rejection by the patient.

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

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

A critical aspect to manufacturing allogeneic T cell product candidates involves gene editing the healthy donor T cells in an effort to avoid GvHD and to limit the patient's immune system from attacking the allogeneic T cells. GvHD results when allogeneic T cells start recognizing the patient's normal tissue as foreign. We use Collectis's TALEN gene-editing technology to inactivate a gene coding for TCR $\alpha$ , a key component of the natural antigen receptor of T cells, to cause the engineered T cells to be incapable of recognizing foreign antigens. Accordingly, when injected into a patient, the intent is for the engineered T cell not to recognize the tissue of the patient as foreign and thus avoid attacking the patient's tissue. In addition, we use TALEN gene editing to inactivate the CD52 gene in donor T cells, which codes for the target of an anti-CD52 monoclonal antibody. Anti-CD52 monoclonal antibodies deplete CD52 expressing T cells in patients while sparing therapeutic allogeneic T cells lacking CD52. By administering an anti-CD52 antibody prior to infusing our product candidates, we believe we have the potential to reduce the likelihood of a patient's immune system from rejecting the engineered allogeneic T cells for a sufficient period of time to enable a window of persistence during which the engineered allogeneic T cells can actively target and destroy the cancer cells.

We rely on an agreement with Collectis for rights to use TALEN and electroporation technology for 15 select cancer targets, including BCMA, FLT3, CD70, DLL3 and other targets included in our pipeline. We also rely on Collectis, through our agreement with Servier, for rights to UCART19 and ALLO-501. Pursuant to our agreement with Servier, we are also dependent on Servier for us to obtain rights to ALLO-501A from Collectis. 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 as 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 our clinical trials of ALLO-501 and ALLO-501A for the treatment of patients with R/R NHL. Other than the agreed-upon global research and development plan for UCART19, we have limited control over the nature or timing of Servier's clinical trials and limited visibility into their day-to-day activities, including with respect to manufacturing and sourcing of raw materials. 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, ALLO-501 and ALLO-501A clinical trials, our expenses may be greater than we currently expect and we may have difficulty progressing our ongoing and planned clinical trials in a timely manner.

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

We have concentrated our research, development and manufacturing efforts on our engineered allogeneic T cell therapy and our future success depends on the successful development of this therapeutic approach. We are in the early stages of developing our platform and there can be no assurance that any development problems we experience in the future will not cause significant delays or unanticipated costs, or that such development problems can be overcome. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical studies or commercializing our products on a timely or profitable basis, if at all. In addition, since we are in the early stages of clinical development, we do not know the doses to be evaluated in pivotal trials or, if approved, commercially. Finding a suitable dose for our cell therapy product candidates as well as ALLO-647 may delay our anticipated clinical development timelines. In addition, our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors.

The clinical study requirements of the FDA, European Medicines Agency (EMA) and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the EMA and FDA for existing autologous CAR



T therapies, such as Kymriah and Yescarta, may not be indicative of what these regulators may require for approval of our therapies. Also, while we expect reduced variability in our products candidates compared to autologous products, we do not have significant clinical data supporting any benefit of lower variability and the use of healthy donor material may create separate variability challenges for us. More generally, approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new product candidates. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the autologous CAR T therapies that have previously been approved. For instance, allogeneic product candidates may result in GvHD not experienced with autologous products. Even if we collect promising initial clinical data of our product candidates, longer-term data may reveal new adverse events or responses that are not durable. Unexpected clinical outcomes would significantly impact our business.

***Our business is highly dependent on the success of UCART19, ALLO-501A and ALLO-715. If we are unable to obtain approval for our lead product candidates and effectively commercialize our lead product candidates for the treatment of patients in approved indications, our business would be significantly harmed.***

Our business and future success depends on our ability to obtain regulatory approval of, and then successfully commercialize, our most advanced product candidates, UCART19, ALLO-501A and ALLO-715. 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, ALLO-501, ALLO-501A and ALLO-715 are among the first allogeneic products to be evaluated in the clinic, the failure of any such product candidate, or the failure of other allogeneic T cell therapies, may impede our ability to develop our product candidates, and significantly influence physicians' and regulators' opinions in regards to the viability of our entire pipeline of allogeneic T cell therapies, particularly if high or uncontrolled rates of GvHD are observed. If significant GvHD events are observed with the administration of our product candidates, or if any of the product candidates is viewed as less safe or effective than autologous therapies, our ability to develop other allogeneic therapies may be significantly harmed.

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

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

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

Undesirable or unacceptable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Approved autologous CAR T therapies and those under development have shown frequent rates of CRS and neurotoxicity, and adverse events have resulted in the death of patients. We expect similar adverse events for allogeneic CAR T product candidates. Our allogeneic CAR T cell product candidates undergo gene engineering by using lentivirus and TALEN nucleases that can cause insertion, deletion, or chromosomal translocation. These changes can cause allogeneic CAR T cells to proliferate uncontrollably and may cause adverse events. In addition, our allogeneic CAR T cell product candidates may cause unique adverse events related to the differences between the donor and patients, such as GvHD or infusion reactions.

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 died in these trials, including deaths that were attributed to UCART19. In the future, patients may experience additional severe 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 and ALLO-501A to cause similar toxicities as UCART19. Other of our allogeneic CAR T product candidates may also cause similar or worse toxicities. For instance, because ALLO-715 may require a higher dose than UCART19 and could be used in a more elderly patient population, it is possible that the risk of GvHD or other adverse events for ALLO-715 could be greater than UCART19.

If unacceptable toxicities arise in the development of our product candidates, we or Servier could suspend or terminate our trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. The data safety monitoring board may also suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk, including risks inferred from other unrelated immunotherapy trials. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. We have trained and expect to have to train medical personnel using CAR T cell product candidates to understand the side effect profile of our product candidates for both our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly.

***Our clinical trials may fail to demonstrate the safety and efficacy of any of our product candidates, which would prevent or delay regulatory approval and commercialization.***

Before obtaining regulatory approvals for the commercial sale of our product candidates, including UCART19, ALLO-501A and ALLO-715, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials, including in any post-approval studies.

There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy, insufficient durability of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as products.

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

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

From time to time, we may publish initial, interim or preliminary data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. For instance, we 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 data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, initial, interim and preliminary data should

be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

***We may not be able to file INDs to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.***

We plan to submit INDs for additional product candidates in the future, including an IND for ALLO-316 by year-end 2020 and an IND for ALLO-605 in 2021. We also plan to submit an IND amendment to initiate the combination trial of ALLO-715 and the SpringWorks' compound, nirogacestat, in the second half of 2020. We cannot be sure that submission of an IND or IND amendment will result in the FDA allowing testing and clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. The manufacturing of allogeneic CAR T cell therapy remains an emerging and evolving field. Accordingly, we expect chemistry, manufacturing and control related topics, including product specification, will be a focus of IND reviews, which may delay the clearance of INDs. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future.

***We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.***

Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned or completed on schedule, if at all. Even if our trials begin as planned, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical study can occur at any stage of testing, and our future clinical studies may not be successful. Events that may prevent successful or timely completion of clinical development include:

- inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical studies;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials;
- difficulty sourcing healthy donor material of sufficient quality and in sufficient quantity to meet our development needs;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching a consensus with regulatory agencies on study design;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (CROs) and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical study sites;
- delays in obtaining required institutional review board (IRB) approval at each clinical study site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives;
- delays in recruiting suitable patients to participate in our clinical studies;
- difficulty collaborating with patient groups and investigators;
- failure by our CROs, other third parties or us to adhere to clinical study requirements;
- failure to perform in accordance with the FDA's good clinical practice (GCP) requirements or applicable regulatory guidelines in other countries;
- transfer of manufacturing processes to any new contract manufacturing organization (CMO) or our own manufacturing facilities or any other development or commercialization partner for the manufacture of product candidates;
- delays in having patients complete participation in a study or return for post-treatment follow-up;
- patients dropping out of a study;
- occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols;

- changes in the standard of care on which a clinical development plan was based, which may require new or additional trials;
- the cost of clinical studies of our product candidates being greater than we anticipate;
- clinical studies of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs;
- delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and
- delays in manufacturing, testing, releasing, validating, or importing/exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing.

Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

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

For our clinical trials of UCART19, ALLO-501 and ALLO-715 and in our planned clinical trials of other product candidates, we and Servier contract with academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. Nonetheless, these centers and hospitals may have difficulty observing patients and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using our product candidates, if approved, on a commercial basis could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of our product candidates may not adequately control the side effects and/or may have a detrimental impact on the efficacy of the treatment. Use of these medicines may increase with new physicians and centers administering our product candidates.

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

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The 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.

Since we only need to conduct a limited number of manufacturing runs to generate clinical supply, the diversity of our supply is limited during clinical trials. As a result, some patients may have antibodies to certain donor specific antigens that may interact with our product candidates, which would render the patients ineligible for treatment.

In addition, prior treatment with rituximab may interfere with ALLO-501 as ALLO-501 contains rituximab recognition domains. Since rituximab is a typical part of a treatment regimen for a patient with NHL, patient eligibility for the ALLO-501 trial may be limited. Patients may also undergo plasmapheresis to remove rituximab prior to infusion of ALLO-501, which may cause separate adverse effects. We have removed the rituximab recognition domains in the second generation of ALLO-501,

known as ALLO-501A, which we believe will potentially facilitate treatment of patients who were recently treated with rituximab. However, we may have difficulty manufacturing or otherwise advancing ALLO-501A.

Our clinical trials will also compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, some of our clinical trial sites are also being used by some of our competitors, which may reduce the number of patients who are available for our clinical trials in that clinical trial site.

Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic cell transplantation or autologous CAR T cell therapies, rather than enroll patients in our clinical trial. Patients eligible for allogeneic CAR T cell therapies but ineligible for autologous CAR T cell therapies due to aggressive cancer and inability to wait for autologous CAR T cell therapies may be at greater risk for complications and death from therapy.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing clinical trial and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

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

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

***The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small.***

The FDA often approves new therapies initially only for use in patients with R/R metastatic disease. We expect to initially seek approval of our product candidates in this setting. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval in earlier lines of treatment. There is no guarantee that our product candidates, even if approved, would be approved for earlier lines of therapy, and, prior to any such approvals, we will have to conduct additional clinical trials, including potentially comparative trials against approved therapies. We are also targeting a similar patient population as autologous CAR T product candidates, including approved autologous CAR T products. Our therapies may not be as safe and effective as autologous CAR T therapies and may only be approved for patients who are ineligible for autologous CAR T therapy.

Our projections of both the number of patients who have the cancers we are targeting, as well as the subset of patients with these cancers in a position to receive second or later lines of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, we expect 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, ALLO-501A and ALLO-715, including ALLO-316 and ALLO-819. Developing, obtaining regulatory approval and commercializing additional CAR T cell product candidates will require substantial additional funding and is prone to the risks

of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process.

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

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

We utilize an anti-CD52 monoclonal antibody as part of a lymphodepletion regimen to be infused prior to infusing our product candidates. While we believe an anti-CD52 antibody may be able to reduce the likelihood of a patient's immune system rejecting the engineered allogeneic T cells for a sufficient period of time to enable a window of persistence during which such engineered allogeneic T cells can actively target and destroy cancer cells, the antibody may not have the benefits that we anticipate and could have adverse effects. For instance, our lymphodepletion regimen, including using an anti-CD52 antibody, will cause a transient and sometimes prolonged immune suppression that is associated with an increased risk of infection.

In the ongoing CALM and PALL trials, we use a commercially available monoclonal antibody, alemtuzumab, that binds CD52. Alemtuzumab is known to have risk of causing certain adverse events. The EMA recently completed a pharmacovigilance review of alemtuzumab in the context of the treatment of multiple sclerosis following reports of immune-mediated conditions and problems affecting the heart and blood vessels, including fatal cases. The EMA has recommended that alemtuzumab should not be used in patients with certain heart, circulation or bleeding disorders or in patients who have autoimmune disorders other than multiple sclerosis. The EMA also recommended that alemtuzumab only be given in a hospital with ready access to intensive care facilities and specialists who can manage serious adverse reactions. We are reviewing the final EMA's recommendations with respect to the use of our proprietary anti-CD52 antibody in our clinical trials, which are currently conducted at specialized centers. If the EMA or other regulatory agencies further limit the use of alemtuzumab or anti-CD52 antibodies, our clinical program would be adversely affected.

To secure our own readily available source of anti-CD52 antibody, we are developing our own monoclonal anti-CD52 antibody, ALLO-647. We are using ALLO-647 in our clinical trial of ALLO-501 and ALLO-715. Subject to regulatory acceptance, Servier may also use ALLO-647 in the Servier sponsored clinical trials of UCART19. However, we may be unable to agree with Servier an appropriate arrangement for the use of ALLO-647. ALLO-647 may also cause adverse events, including but not limited to those events that alemtuzumab may cause. In addition, we are exploring various dosing strategies of ALLO-647 in our clinical trials, and higher doses of ALLO-647 may increase the risk of adverse events.

If we are unable to successfully develop and manufacture ALLO-647 in the timeframe we anticipate, or at all, or if regulatory authorities do not approve the use of ALLO-647 in combination with our allogeneic T cell product candidates, we may be unable to source alemtuzumab and our engineered allogeneic T cell product candidates may be less effective, which could result in delays in our product development efforts and/or the commercial potential of our product candidates.

***We intend to operate our own manufacturing facility, which will require significant resources and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates.***

We may not be able to achieve clinical or commercial manufacturing and cell processing on our own or at our CMO, including mass-producing off-the-shelf product to satisfy demands for any of our product candidates. While we believe the manufacturing and processing approaches are appropriate to support our clinical product development, we have limited experience in managing the allogeneic T cell engineering process, and our allogeneic processes may be more difficult or more expensive than the approaches taken by our competitors. We cannot be sure that the manufacturing processes employed by us or the technologies that we incorporate for manufacturing will result in T cells that will be safe and effective.

In February 2019, we entered into a lease for approximately 118,000 square feet to develop a state-of-the-art cell therapy manufacturing facility in Newark, California. The facility requires substantial improvements and there can be no assurance that we will complete the build-out of our manufacturing facility in a timely manner or at all. We also do not yet have sufficient information to reliably estimate the cost of the clinical and commercial manufacturing and processing of our product candidates, and the actual cost to manufacture and process our product candidates could materially and adversely affect

the commercial viability of our product candidates. In addition, the ultimate clinical and any commercial dose will affect our ability to scale and our costs per dose. For instance, because ALLO-715 may require a higher dose than ALLO-501, it is possible that it may be more difficult to scale ALLO-715 production. As a result, we may never be able to develop a commercially viable product. The commercial manufacturing facility we build will also require FDA approval, which we may never obtain. Even if approved, we would be subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with current good manufacturing practices (cGMPs), and other government regulations.

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

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

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

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

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

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

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

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

The CALM and PALL clinical trials are currently being conducted in the United States and multiple countries in Europe, and we plan to globally develop our future product candidates. Accordingly, we expect that we will be subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- differing standards for the conduct of clinical trials;

- increased difficulties in managing the logistics and transportation of storing and shipping product candidates produced in the United States and shipping the product candidate to the patient abroad;
- import and export requirements and restrictions;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems, and price controls;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from natural or man-made disasters, including earthquakes, tsunamis, fires or medical epidemics, or 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, and with Notch Therapeutics Inc. (Notch), based in Canada, may materially adversely affect our ability to attain or maintain profitable operations.

***We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.***

The biopharmaceutical industry, and the immuno-oncology industry specifically, is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products.

Specifically, engineered T cells face significant competition from multiple companies. Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see "Item 1. Business—Competition" in our Annual Report.

***We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.***

Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel, including our Executive Chairman, our President and Chief Executive Officer, our Chief Financial Officer, our Executive Vice President of Research & Development and Chief Medical Officer, and our Chief Technical Officer. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business.



We conduct substantially all of our operations at our facilities in South San Francisco. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all.

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

***We have grown rapidly and will need to continue to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of February 24, 2020, we had 205 full-time employees. As our development and commercialization plans and strategies develop, and as we continue to transition into operating as a public company, we have rapidly expanded our employee base and expect to add managerial, operational, sales, research and development, marketing, financial and other personnel. Current and future growth imposes significant added responsibilities on members of management, including:

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

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

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants. In September 2019, we terminated support services previously provided by Pfizer, and our internal build-out of such services may disrupt our operations and be more expensive than we expect. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. We may also be subject to penalties or other liabilities if we mis-classify employees as consultants. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop, manufacture and commercialize our product candidates and, accordingly, may not achieve our research, development, manufacturing and commercialization goals.

***We may form or seek 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 agreements with Servier, Notch and SpringWorks require significant research and development that may not result in the development and commercialization of product candidates. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction.

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

We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, including our acquisition of CAR T cell assets from Pfizer, licenses with Cellectis, Servier and Notch, 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 development and manufacture of our product candidates, including UCART19, ALLO-501, ALLO-501A 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 December 31, 2019, we had \$588.9 million in cash, cash equivalents and investments. Changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may also need to raise additional capital sooner than we currently anticipate if we choose to expand more rapidly than we presently plan. In any event, we will require additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities.

We cannot be certain that additional funding will be available on acceptable terms, or at all. We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our license agreements may also be terminated if we are unable to meet the

payment obligations under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

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

Our internal computer systems and those of our CROs, collaborators, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, cybersecurity threats, and telecommunication and electrical failures. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

Our operations, and those of our CMO, CROs and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

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

These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of identifiable patient information. The U.S. healthcare laws and regulations that may affect our ability to operate include, but are not limited to:

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

Additionally, we may be subject to state, local and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope. For example, we may be subject to the following: state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, or that apply regardless of payor; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the

relevant compliance guidance promulgated by the federal government; state and local laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state laws that require the reporting of information related to drug pricing; state and local laws requiring the registration of pharmaceutical sales 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 significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

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

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

The GDPR applies extraterritorially, and we may be subject to the GDPR because of our data processing activities that involve the personal data of individuals located in the European Union, such as in connection with our EU clinical trials. Failure to comply with the requirements of the GDPR and the applicable national data protection laws of the EU member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. GDPR regulations may impose additional responsibility and liability in relation to the personal data that we process and we may be required to put in place additional mechanisms to ensure compliance with the new data protection rules. This may be onerous and may interrupt or delay our development activities, and adversely affect our business, financial condition, results of operations and prospects.

Additionally, California recently enacted legislation that has been dubbed the first “GDPR-like” law in the United States. Known as the California Consumer Privacy Act (CCPA), it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosures to California consumers, provide such consumers new ways to opt-out of certain sales of personal information, and allow for a new cause of action for data breaches. As our business progresses, the CCPA may significantly impact our business activities and exemplifies the vulnerability of our business to evolving regulatory environment related to personal data and protected health information.

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

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

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

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

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

***Legal, regulatory, political and economic uncertainty surrounding the exit of the U.K. from the European Union may be a source of instability in international markets, create significant currency fluctuations, adversely affect operations in the U.K. and pose additional risks to our business.***

Following the result of a referendum in 2016, the U.K. left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the U.K. and the EU, the U.K. will be subject to a transition period until December 31, 2020 (Transition Period), during which EU rules will continue to apply. Negotiations between the U.K. and the EU are expected to continue in relation to the customs and trading relationship between the U.K. and the EU following the expiry of the Transition Period. Such a withdrawal from the EU is unprecedented, and it is unclear how

the U.K.'s access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our business.

The uncertainty concerning the U.K.'s legal, regulatory, political and economic relationship with the EU after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise). It could also lead to a period of considerable uncertainty in relation to the regulatory process for drug development and approval in Europe, and make it more costly or difficult to advance our product candidates in the EU and U.K.

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

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

**Risks Related to Our Reliance on Third Parties**

***We rely and will continue to rely on third parties, including Servier, to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.***

We depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical and clinical trials under agreements with us. In addition, we depend on our collaborator, Servier, to sponsor and lead the conduct of the CALM and PALL clinical trials.

We negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices (GCPs), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

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

obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

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

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

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

While we have leased space to build a manufacturing facility, we must currently rely on outside vendors to manufacture supplies and process our product candidates. We do not have long-term agreements in place with CMOs for the manufacture of our cell therapies or of ALLO-647. If we are unable to contract with CMOs on acceptable terms or at all, our clinical development program would be delayed and our business would be significantly harmed.

We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to achieve manufacturing and processing and may be unable to create an inventory of mass-produced, off-the-shelf product to satisfy demands for any of our product candidates.

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

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

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

Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. For instance, our CMO has certain responsibilities for storage of raw materials, and the damage or loss of such raw materials could materially impact our ability to manufacture and supply our product candidates. Each of



these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm.

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

Unlike autologous CAR T companies, we are reliant on receiving healthy donor material to manufacture our product candidates. Healthy donor T cells vary in type and quality, and this variation makes producing standardized product candidates more difficult and makes the development and commercialization pathway of those product candidates more uncertain. We have developed a screening process designed to enhance the quality and consistency of T cells used in the manufacture of our CAR T cell product candidates, but our screening process may fail to identify suitable donor material and we may discover failures with the material after production.

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

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

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

In addition, many of our suppliers normally support blood-based hospital businesses and generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill-equipped to support our needs, especially in non-routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also face competition for supplies from other cell therapy companies. Such competition may make it difficult for us to secure raw materials or the testing of such materials on commercially reasonable terms or in a timely manner.

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

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

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any

insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations.

## **Risks Related to Government Regulation**

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

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

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

We may also experience delays in completing planned clinical trials for a variety of reasons, including delays related to:

- obtaining regulatory authorization to begin a trial, if applicable;
- the availability of financial resources to commence and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an independent IRB;
- recruiting suitable patients to participate in a trial;
- having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- adding new clinical trial sites; or
- manufacturing sufficient quantities of qualified materials under cGMPs and delivering product candidates for use in clinical trials.

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

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

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

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted as part of the 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.

Also, the FDA department that reviews ALLO-647 is different than the department that reviews our CAR T cell product candidates. As we are concurrently developing ALLO-647 to be used as part of the lymphodepletion regimen for our CAR T cell product candidates, mapping a path for dual approval of ALLO-647 and any of our CAR T cell product candidates and coordinating concurrent review within the FDA create additional regulatory uncertainty for us and may delay the development of our product candidates.

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

applicable to our UCART19 product candidate; however, this recommendation is not definitive until UCART19 obtains regulatory approval for commercialization.

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

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

***The FDA may disagree with our regulatory plan and we may fail to obtain regulatory approval of our product candidates.***

If and when our ongoing and planned Phase 1 clinical trials for UCART19, ALLO-501A and ALLO-715 are completed and, assuming positive data, we expect to advance to potential registrational trials. The general approach for FDA approval of a new biologic or drug is for the sponsor to provide dispositive data from two well-controlled, Phase 3 clinical studies of the relevant biologic or drug in the relevant patient population. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. We expect registrational trials for UCART19, ALLO-501A and ALLO-715 to be designed to evaluate the efficacy of the product candidate in an open-label, non-comparative, two-stage, pivotal, multicenter, single-arm clinical trial in patients who have exhausted available treatment options. If the results are sufficiently compelling, we intend to discuss with the FDA submission of a BLA for the relevant product candidate. However, we do not have any agreement or guidance from the FDA that our regulatory development plans will be sufficient for submission of a BLA. For example, the FDA may require that we conduct a comparative trial against an approved therapy including potentially an approved autologous T cell therapy, which would significantly delay our development timelines and require substantially more resources. In addition, the FDA may only allow us to evaluate patients that have failed or who are ineligible for autologous therapy, which are extremely difficult patients to treat and patients with advanced and aggressive cancer, and our product candidates may fail to improve outcomes for such patients.

Given the molecular similarities between UCART19, ALLO-501 and ALLO-501A, we may have additional difficulties progressing any clinical trial of ALLO-501A, if emerging data from the clinical trials of ALLO-501 or UCART19 have safety or other issues.

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

ALLO-647 will also require regulatory review prior to its use in new clinical trials and the FDA may not accept the use of ALLO-647 in our clinical trials in a timely manner or at all. In addition, we cannot be certain we will be able to successfully obtain regulatory approval of ALLO-647 in a timely manner or at all. Any delays to ALLO-647 approval could delay any approval or commercialization of our allogeneic T cell product candidates. Additionally, regulatory authorities may seek to understand the contribution of the lymphodepletion regimen, including the use of an anti-CD52 antibody, to any treatment effect.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

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

***We may seek orphan drug designation for some or all of our product candidates across various indications, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced.***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product.

We may seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if approved. In addition, although we may seek orphan drug designation for other product candidates, we may never receive such designations.

***Regenerative Medicine Advanced Therapy designation, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.***

We may seek Regenerative Medicine Advanced Therapy (RMAT) designation for one or more of our product candidates. In 2017, the FDA established the RMAT designation to expedite review of a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which

preliminary clinical evidence indicates that the potential to address unmet medical needs for such a disease or condition. RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. There is no assurance that we will be able to obtain RMAT designation for any of our product candidates. RMAT designation does not change the FDA's standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

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

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

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

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

Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a risk evaluation and mitigation strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label may be subject to significant liability. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third-party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

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

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

***Negative public opinion and increased regulatory scrutiny of genetic research and therapies involving gene editing may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates.***

The gene-editing technologies that we use are novel. Public perception may be influenced by claims that gene editing is unsafe, and products incorporating gene editing may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in our targeted diseases prescribing our product candidates as treatments in lieu of, or in addition to, existing, more familiar, treatments for which greater clinical data may be available. Any increase in negative perceptions of gene editing may result in fewer physicians prescribing our treatments or may reduce the willingness of patients to utilize our treatments or participate in clinical trials for our product candidates. In addition, given the novel nature of gene-editing and cell therapy technologies, governments may place import, export or other restrictions in order to retain control or limit the use of the technologies. Increased negative public opinion or more restrictive government regulations either in the United States or internationally, would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for such product candidates.

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

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

- the clinical indications for which our product candidates are approved;
- physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment;

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

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

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

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

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

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 payors 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 payors, 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.

There remain legal and political challenges to certain aspects of the Affordable Care Act. Since January 2017, the U.S. President has signed two Executive Orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. In December 2017, Congress repealed the tax penalty for an individual's failure to maintain Affordable Care Act-mandated health insurance, commonly known as the "individual mandate", as part of the Tax Cuts and Jobs Act of 2017 (Tax Act). In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the Affordable Care Act's mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. The Bipartisan Budget Act of 2018 (BBA), among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In December 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how this decision, future decisions, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business.

Further legislation or regulation could be passed that could harm our business, financial condition and results of operations. Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint

Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least \$1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2029, unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and federal and state legislative activity designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for drugs. At the federal level, the U.S. President's administration's budget proposal for fiscal year 2020 contains further drug price control measures that could be enacted during the budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the current U.S. President's administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization 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 Cellectis for gene-editing technology that is necessary to produce our engineered T cells. In addition, we are reliant on Servier in-licensing from Cellectis some of the intellectual property rights they are licensing to us, including certain intellectual property rights relating to UCART19, ALLO-501 and ALLO-501A. To the extent these licensors fail to meet their obligations under their license agreements, which we are not in control of, we may lose the benefits of our license agreements with these licensors. In the future, we may also enter into additional license agreements that are material to the development of our product candidates.

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

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

If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are generally also subject to all of the same risks with respect to protection of intellectual property that we license, as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

***If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.***

We rely upon a combination of patents, trade secret protection and license agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

We have an exclusive collaboration with Servier to develop and commercialize UCART19, ALLO-501 and ALLO-501A, and we hold the commercial rights to these product candidates in the United States. We also have an exclusive worldwide license from Cellectis to its TALEN gene-editing technology for the development of allogeneic T cell product candidates directed against 15 different cancer antigens. Our collaboration with Servier gives us access to TALEN gene-editing technology for all product candidates under the Servier Agreement. Certain intellectual property which is covered by these agreements may have been developed with funding from the U.S. government. If so, our rights in this intellectual property may be subject to certain research and other rights of the government.

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

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

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

by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products “off-label.” Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

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

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

***Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information.***

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. Although we require all of our employees to assign their inventions to us, and require all of our employees and key consultants who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

***Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts and our ability to commercialize our product candidates.***

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we infringe their patents or are otherwise employing their proprietary technology without authorization and may sue us. We are aware of several U.S. patents held by third parties relating to certain CAR compositions of matter and their methods of use. Generally, conducting clinical trials and other development activities in the United States is not considered an act of infringement. If and when UCART19, ALLO-501A, ALLO-715 or another CAR-based product candidate is approved by the FDA, third parties may then seek to enforce their patents by filing a patent infringement lawsuit against us. Patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is “clear and convincing,” a heightened standard of proof. We may not be able to prove in litigation that any patent enforced against us is invalid.

Additionally, there may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may be alleged to infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held not infringed, unpatentable, invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held not infringed, unpatentable, invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business and may impact our reputation. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys’ fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

***We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in-licenses.***

Presently we have rights to the intellectual property, through licenses from third parties and under patent applications that we own or will own, that we believe will facilitate the development of our product candidates. Because our programs may involve additional product candidates that may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights.

We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, which would harm our business. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

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

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

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

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

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

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

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

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

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

We or our licensors may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product

candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we or our licensors are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

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

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

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

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may

not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.***

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

### **Risks Related to Ownership of Our Common Stock**

***The price of our stock has been and may continue to be volatile, and you could lose all or part of your investment.***

Prior to our IPO in October 2018, there was no public market for our common stock. We cannot assure you that an active, liquid trading market for our shares will develop or persist. You may not be able to sell your shares quickly or at a recently reported market price if trading in our common stock is not active. The trading price of our common stock following our IPO has been and is likely to continue to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section, these factors include:

- the commencement, enrollment or results of our ongoing and planned clinical trials of our product candidates or any future clinical trials we or Servier may conduct, or changes in the development status of our product candidates;
- our or Servier's decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial;
- adverse results or delays in clinical trials;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- our failure to commercialize our product candidates;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning the manufacture or supply of our product candidates;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to immuno-oncology or related to the use of our product candidates or pre-conditioning regimen;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;



- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our disclosure controls or internal controls;
- disagreements with our auditor or termination of an auditor engagement;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- changes in the structure of healthcare payment systems;
- significant lawsuits, including patent or stockholder litigation;
- 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 any future cash flow or earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

***We will incur significant costs as a result of operating as a public company, and our management will be required to devote substantial time to various 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 time, however we are no longer an emerging growth company as of December 31, 2019 and expect to incur additional compliance-related expenses as a result.

Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may also 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, these rules and regulations make it difficult and expensive for us to maintain director and officer liability insurance. 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.

Failure to comply with the rules and regulations applicable to us could have serious consequences, including civil and criminal penalties. In addition, our reputation and our ability to raise additional capital would be harmed.

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

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

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

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

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

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

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

Pursuant to the 2018 Plan, our management is authorized to grant stock options and RSU awards to our employees, directors and consultants. We have registered on Form S-8 all shares of common stock that are issuable under our 2018 Plan. Additionally, the number of shares of our common stock reserved for issuance under the 2018 Plan will automatically increase on January 1 of each year and continuing through and including January 1, 2028, by 5% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

***We have broad discretion in the use of our cash reserves and may not use them effectively.***

Our management has broad discretion in the application of our cash reserves. A number of factors will determine the ultimate use of our cash reserves, and our management may not be able to apply these funds effectively. Pending their use, we may invest these funds in short-term, investment-grade, interest-bearing securities, which may not yield a favorable return and may lose value.

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

**Item 1B. Unresolved Staff Comments.**

None.

**Item 2. Properties.**

Our corporate headquarters are located in South San Francisco, California, which consists of approximately 68,000 square feet for office and laboratory space. The lease for our headquarters commenced March 1, 2019 and has an initial 10-year term expiring on June 15, 2023. We entered into an additional lease in October 2018 for approximately 14,943 square feet of office and laboratory space in South San Francisco near our headquarters. This lease has an initial term of ten years and four months and commenced on November 1, 2018.

In February 2019, we entered into a lease for approximately 118,000 square feet to develop a state-of-the-art cell therapy manufacturing facility in Newark, California. The lease has an initial term of 15 years and eight months. We expect the lease to commence in March 2020.

We believe that our existing facilities and other available properties will be sufficient for our needs for the foreseeable future.

**Item 3. Legal Proceedings.**

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**PART II**

**Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.**

Our common stock has been listed on The Nasdaq Global Select Market under the symbol “ALLO” since October 11, 2018. Prior to that date, there was no public trading market for our common stock.

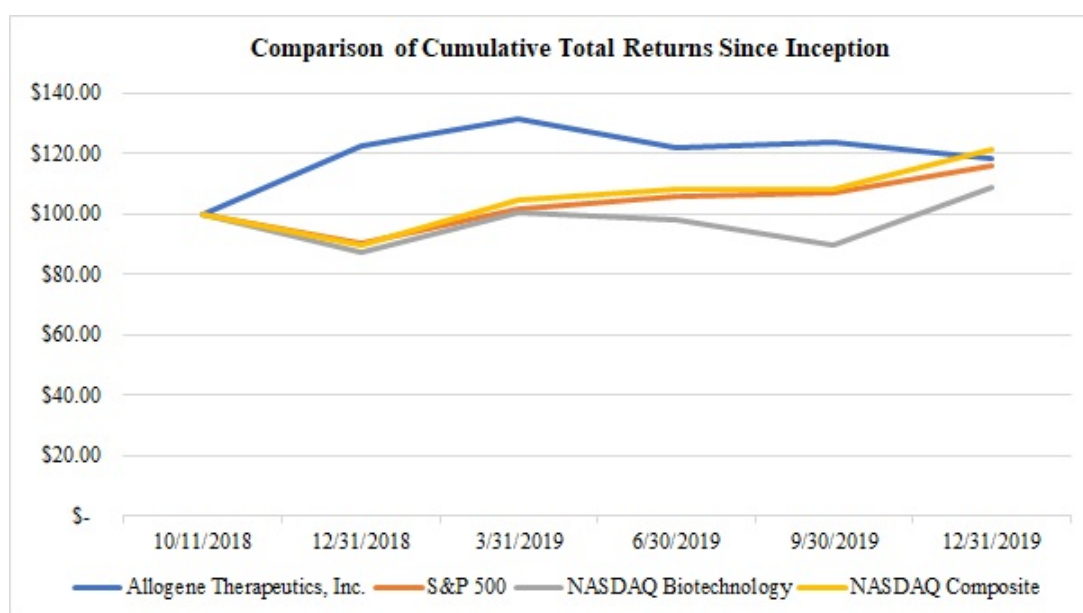
**Holders of Common Stock**

As of February 27, 2020, there were approximately 74 holders of record of our common stock.

**Stock Performance Graph**

*This performance graph shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.*

The following graph shows the value of an investment of \$100 from October 11, 2018 (the date our common stock commenced trading on The Nasdaq Global Select Market) through December 31, 2019, in our common stock, the Standard & Poor’s 500 Index (S&P 500), the Nasdaq Biotechnology Index, and Nasdaq Composite Index. The historical stock price performance of our common stock shown in the performance graph is not necessarily indicative of future stock price performance.



**Cumulative Total Return date ended**

	10/11/2018	12/31/2018	3/31/2019	6/30/2019	9/30/2019	12/31/2019
Allogene Therapeutics, Inc.	\$ 100.00	\$ 122.41	\$ 131.41	\$ 122.05	\$ 123.91	\$ 118.09
S&P 500	\$ 100.00	\$ 90.28	\$ 101.85	\$ 105.94	\$ 106.85	\$ 116.35
Nasdaq Biotechnology	\$ 100.00	\$ 87.25	\$ 100.68	\$ 98.26	\$ 89.66	\$ 108.54
Nasdaq Composite	\$ 100.00	\$ 89.81	\$ 104.62	\$ 108.37	\$ 108.27	\$ 121.45

**Dividend Policy**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

#### **Use of Proceeds from Initial Public Offering of Common Stock**

In October 2018, we completed our initial public offering, and sold 18,000,000 shares of our common stock at a price of \$18.00 per share 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. Additionally, the underwriters exercised their option to purchase additional shares for an additional 2,700,000 shares at \$18.00 per share. As a result of our IPO, we raised a total of approximately \$343.3 million in net proceeds after deducting underwriting discounts and commissions of \$26.1 million and offering expenses of \$3.2 million. Upon completion of our IPO, (1) all outstanding shares of our Series A convertible preferred stock, were converted into 61,655,922 shares of common stock and, (2) we issued 7,856,176 shares of common stock as a result of the automatic conversion of the \$120.2 million aggregate principal amount of convertible promissory notes sold in September 2018.

Upon receipt, the net proceeds from our IPO were held in cash, cash equivalents and investments. As of December 31, 2019, we have not used any of the net proceeds from our IPO. The net proceeds from our IPO will be used, together with our cash and cash equivalents, short-term and long-term investments, to fund continued advancement of our product pipeline, with the balance to be used to fund working capital and other general corporate purposes, which may include licensing, acquiring or investing in complementary businesses, technologies, products or assets.

#### **Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

None.

#### **Item 6. Selected Financial Data.**

The selected statements of operations and comprehensive loss data for the periods presented and the selected balance sheet data as of the dates presented are derived from our financial statements appearing elsewhere in this Annual Report.

Our historical results are not necessarily indicative of the results that can be expected in the future. The selected historical financial data below should be read in conjunction with the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements and related notes appearing elsewhere in this Annual Report.

	Year Ended December 31,		Period from November 30, 2017 (Inception) to December 31,
	2019	2018	2017
<b>Statements of operations and comprehensive loss data:</b>			
(in thousands, except share and per share amounts)			
<b>Operating expenses:</b>			
Research and development	\$ 144,535	\$ 151,860	\$ —
General and administrative	57,473	40,982	2
Total operating expenses	202,008	192,842	
Loss from operations	(202,008)	(192,842)	(2)
<b>Other (expense) income, net:</b>			
Change in fair value of convertible note payable	—	(21,211)	—
Interest expense	—	(3,358)	—
Interest and other income, net	17,351	5,789	—
Other expenses	(268)	—	—
Total other (expense) income, net	17,083	(18,780)	—
Loss before income taxes	(184,925)	(211,622)	(2)
Benefit from income taxes	331	117	—
Net loss	(184,594)	(211,505)	(2)
Other comprehensive income	839	306	—
Net comprehensive loss	\$ (183,755)	\$ (211,199)	\$ (2)
Net loss attributable to common stockholders-basic and diluted <sup>1</sup>	\$ (1.83)	\$ (7.31)	\$ 0.00
Weighted-average number of common shares used in net loss per share applicable to common stockholders basic and diluted	101,061,149	28,948,386	26,249,993

<sup>1</sup> See the statements of operations and comprehensive loss and Note 17 to our financial statements for further details on the calculation of net loss per share, basic and diluted, and the weighted-average number of shares used in the computation of the per share amounts.

	As of December 31		
	2019	2018	2017
<b>Balance sheet data:</b>			
(in thousands)			
Cash, cash equivalents and investments	\$ 588,855	\$ 721,350	\$ —
Working capital <sup>2</sup>	511,497	438,523	(2)
Total assets	717,802	773,855	—
Total liabilities	88,779	70,691	2
Accumulated deficit	(396,122)	(211,528)	(23)
Total stockholders' equity (deficit)	629,023	703,164	(2)

<sup>2</sup> We define working capital as current assets less current liabilities. See our financial statements for further details regarding our current assets and current liabilities.

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion contains management's discussion and analysis of our financial condition and results of operations and should be read together with "Selected Financial Data" and the historical consolidated financial statements and the notes thereto included in "Financial Statements and Supplementary Data". This discussion contains forward-looking statements that reflect our plans, estimates and beliefs and involve numerous risks and uncertainties, including but not limited to those described in the "Risk Factors" section of this Annual Report. Actual results may differ materially from those contained in any forward-looking statements. You should carefully read "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

### Overview

We are a clinical stage immuno-oncology company pioneering the development and commercialization of genetically engineered allogeneic T cell therapies for the treatment of cancer. We are developing a pipeline of off-the-shelf T cell product candidates that are designed to target and kill cancer cells. Our engineered T cells are allogeneic, meaning they are derived from healthy donors for intended use in any patient, rather than from an individual patient for that patient's use, as in the case of autologous T cells. We believe this key difference will enable us to deliver readily available treatments faster, more reliably, at greater scale, and to more patients.

We have a deep pipeline of allogeneic chimeric antigen receptor (CAR) T cell product candidates targeting multiple promising antigens in a host of hematological malignancies and solid tumors. In collaboration with Servier, we are developing UCART19, ALLO-501 and ALLO-501A, CAR T cell product candidates targeting CD19. Servier is sponsoring two Phase 1 clinical trials of UCART19 in patients with relapsed/refractory (R/R) B-cell precursor acute lymphoblastic leukemia (ALL), one for adult patients (the CALM trial) and one for pediatric patients (the PALL trial).

We are sponsoring a Phase 1 clinical trial (the ALPHA trial) of ALLO-501 in patients with R/R non-Hodgkin lymphoma (NHL). We expect to report initial data from the trial in the second quarter of 2020. We plan to use the clinical data from ALLO-501 to accelerate the development of the second-generation version of ALLO-501, known as ALLO-501A. We have removed rituximab recognition domains in ALLO-501A, which we believe will potentially facilitate treatment of more patients, as rituximab is a typical part of a treatment regimen for a patient with NHL. In December 2019, the FDA cleared our IND to initiate a Phase 1/2 clinical trial for ALLO-501A (the ALPHA2 trial) and we plan to initiate the trial in the second quarter of 2020, subject to completing the manufacturing of ALLO-501A.

In May 2019, the FDA cleared our IND to initiate a Phase 1 clinical trial (the UNIVERSAL trial) of ALLO-715, an allogeneic CAR T cell product candidate targeting B-cell maturation antigen (BCMA), in adult patients with R/R multiple myeloma. The UNIVERSAL trial was initiated in the third quarter of 2019 and is ongoing.

Since inception, we have had significant operating losses. Our net loss was \$184.6 million for the year ended December 31, 2019. As of December 31, 2019, we had an accumulated deficit of \$396.1 million. As of December 31, 2019, we had \$588.9 million in cash and cash equivalents and investments. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase.

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

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

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

### ***Research Collaboration and License Agreement with Cellectis***

In June 2014, Pfizer entered into a Research Collaboration and License Agreement with Cellectis S.A. (Cellectis). In April 2018, Pfizer assigned the agreement to us pursuant to the Pfizer Agreement. In March 2019, we terminated the agreement with Cellectis and entered into a new license agreement with Cellectis. See Note 7 to our financial statements included elsewhere in this report for further descriptions of the prior agreement with Cellectis and the new license agreement with Cellectis.

### ***Exclusive License and Collaboration Agreement With Servier***

In October 2015, Pfizer entered into an Exclusive License and Collaboration Agreement (Servier Agreement) with Servier to develop, manufacture and commercialize certain allogeneic anti-CD19 CAR products, including UCART19, in the United States with the option to obtain the rights over certain additional allogeneic anti-CD19 CAR product candidates. In April 2018, Pfizer assigned the agreement to us pursuant to the Pfizer Agreement. See Note 7 to our financial statements included elsewhere in this report for further description of the Servier Agreement.

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



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

The Notch Agreement includes a research collaboration to conduct research and pre-clinical development activities to generate engineered cells directed to our exclusive targets, which will be conducted in accordance with an agreed research plan and budget under the oversight of a joint development committee. In connection with the execution of the Notch Agreement, we made an upfront payment to Notch of \$10.0 million. In addition, we made a \$5.0 million investment in Notch's series seed convertible preferred stock, resulting in us having a 25% ownership interest in Notch's outstanding capital stock on a fully diluted basis immediately following the investment. See Note 7 to our financial statements included elsewhere in this report for further description of the Notch 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 we obtained from Pfizer 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 provided us with certain facilities and facility management services. The services were provided by certain employees of Pfizer as independent contractors of Allogene. We believe that it was 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 the TSA was terminated in September 2019.

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

#### ***Operating Expenses***

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

To date, our research and development expenses have related primarily to discovery efforts, preclinical and clinical development, and manufacturing of our product candidates. Research and development expenses for the year ended December 31, 2019 included costs associated with our clinical and preclinical stage pipeline candidates and research into newer technologies. The most significant research and development expenses for the year relate to costs incurred for the development of our most advanced product candidates, UCART19, ALLO-501, ALLO-501A and ALLO-715, 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 the production of clinical materials, including fees paid for raw materials and to contract manufacturers;
- laboratory and vendor expenses related to the execution of preclinical and clinical trials;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- facilities and other expenses, which include expenses for rent and maintenance of facilities, depreciation and amortization expense and other supplies; and
- other significant research and development costs include overhead costs.

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

We are required to reimburse Servier for 60% of the costs associated with the development of UCART19, including for the CALM and PALL clinical trials. We accrue for costs incurred by monitoring the status of the CALM and PALL clinical trials and the invoices received from Servier. We adjust our accrual as actual costs become known. Servier is required to reimburse us for 40% of the costs associated with the development of ALLO-501 and ALLO-501A. Collaboration expenses and cost reimbursement are recorded on a net basis as a research and development expense in our statements of operations and comprehensive loss.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase in the future as our UCART19, ALLO-501, ALLO-501A and ALLO-715 clinical programs progress and as we seek to initiate clinical trials of additional product candidates. The cost of advancing our manufacturing process as well as the cost of manufacturing product candidates for clinical trials are included in our research and development expense. We also expect to incur increased research and development expenses as we selectively identify and develop additional product candidates. However, it is difficult to determine with certainty the duration and completion costs of our current or future preclinical programs and clinical trials of our product candidates.

The duration, costs and timing of clinical trials and development of our product candidates will depend on a variety of factors that include, but are not limited to, the following:

- per patient trial costs;
- biomarker analysis costs;
- the cost and timing of manufacturing for the trials;
- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the total number of cells that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up; and
- the efficacy and safety profile of the product candidates.

In the case of UCART19, we are also dependent on Servier's ability to manage the CALM and PALL clinical trials. In addition, the probability of success for each product candidate will depend on numerous factors, including safety, efficacy, competition, manufacturing capability and commercial viability. We will determine which programs to pursue and how much to fund each program in response to the scientific and clinical success of each product candidate, as well as an assessment of each product candidate's commercial potential.

Because our product candidates are still in clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of product candidates or whether, or when, we may achieve profitability.

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

General and administrative expenses consist primarily of salaries and other staff-related costs, including stock-based compensation for options and restricted stock units granted. General and administrative expenses also include stock-based compensation expense related to the modification of shares of common stock issued to our founders to include vesting conditions. Other significant costs include costs relating to facilities and overhead costs, legal fees relating to corporate and patent matters, insurance, investor relations costs, fees for accounting and consulting services, information technology, and other general and administrative costs. General and administrative costs are expensed as incurred, and we accrue for services provided by third parties related to the above expenses by monitoring the status of services provided and receiving estimates from our service providers, and adjusting our accruals as actual costs become known.

We expect our general and administrative expenses to increase over the next several years to support our continued research and development activities, manufacturing activities, potential commercialization of our product candidates and the increased costs of operating as a public company, including additional compliance-related expenses as a result of no longer being an emerging growth company. These increases are anticipated to include increased costs related to the hiring of additional personnel, developing 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.

***Other (expense) income, net:***

***Change in Fair Value of 2018 Notes***

In September 2018, we sold and issued an aggregate of \$120.2 million in convertible promissory notes (2018 Notes) and received net cash proceeds of \$116.8 million. We elected on issuance to account for the 2018 Notes at fair value until their settlement. In the prior 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.

***Other Expense***

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

**Results of Operations**

For the period from November 30, 2017 (inception) to December 31, 2017, we incurred \$2,000 in start-up costs to establish our company. Principal operations commenced in April 2018 when we acquired certain assets from Pfizer and completed a Series A and A-1 preferred stock financing. Due to our limited operations in 2017, the following discussion does not contain a comparison of the results of operations for the period from November 30, 2017 (inception) to December 31, 2017.

***Comparison of the Years Ended December 31, 2019 and 2018***

The following sets forth our results of operations for the years ended December 31, 2019 and 2018 (in thousands):

	Year Ended December 31,		Change
	2019	2018	
Operating expenses:			
Research and development	\$ 144,535	\$ 151,860	\$ (7,325)
General and administrative	57,473	40,982	16,491
Total operating expenses	202,008	192,842	9,166
Loss from operations	(202,008)	(192,842)	(9,166)
Other (expense) income, net:			
Change in fair value of convertible note payable	—	(21,211)	21,211
Interest expense	—	(3,358)	3,358
Interest and other income, net	17,351	5,789	11,562
Other expense	(268)	—	(268)
Total other income (expense), net	17,083	(18,780)	35,863
Loss before income taxes	(184,925)	(211,622)	26,697
Benefit from income taxes	331	117	214
Net loss	(184,594)	(211,505)	26,911

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

Research and development expenses were \$144.5 million and \$151.9 million for the years ended December 31, 2019 and 2018, respectively. The net decrease of \$7.3 million in research and development expenses during this period was primarily due to \$109.4 million in expenses related to the acquired in-process research and development assets with no alternative future use, acquired from Pfizer in April 2018. This was offset by a \$102.1 million increase, driven primarily by increased external costs related to the advancement of our pipeline candidates of \$44.6 million, increased personnel related costs of \$40.8 million, including an increase of \$18.0 million in stock-based compensation expense, and increased allocated building rent and facilities costs of \$19.2 million, offset by a decrease of \$4.0 million in Pfizer TSA costs.

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

General and administrative expenses were \$57.5 million and \$41.0 million for the years ended December 31, 2019 and 2018, respectively. The net increase of \$16.5 million was primarily due to a \$18.6 million increase in personnel related costs, including an increase of \$9.7 million in stock-based compensation expense, and increased legal and professional services of \$2.7 million. This was offset by a \$5.1 million decrease due to a greater proportion of facilities costs being allocated to research and development expenses and a \$1.5 million decrease in expenses incurred under the Pfizer TSA.

### ***Change in Fair Value of 2018 Notes***

The change in fair value of convertible notes was zero and \$21.2 million for the years ended December 31, 2019 and 2018, respectively. The decrease of \$21.2 million was due to the accretion of the 2018 Notes to their fair value from the date of issuance at \$120.2 million to the fair value upon settlement of \$141.4 million which occurred in 2018. There was no comparative transaction in the year ended December 31, 2019.

### ***Interest Expense***

Interest expense of \$3.4 million for the year ended December 31, 2018 consists of debt issuance costs that were expensed on issuance of the 2018 Notes. There was no comparative transaction in the year ended December 31, 2019.

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

Interest and other income, net was \$17.4 million and \$5.8 million for the years ended December 31, 2019 and 2018 respectively. The \$11.6 million increase was due to interest earned on our cash equivalents and investments as our combined cash, cash equivalents and investments interest earning balance was higher on average during the 12 months ended December 31, 2019 compared to the 12 months ended December 31, 2018.

## Liquidity, Capital Resources and Plan of Operations

To date, we have incurred significant net losses and negative cash flows from operations. As of December 31, 2019, we had \$588.9 million in cash, cash equivalents and investments. We believe that the aggregate of our current cash and cash equivalents and investments available for operations will be sufficient to fund our operations for at least the next 12 months from the date this Annual Report on Form 10-K is filed with the SEC.

Our operations have been financed primarily by net proceeds from the sale and issuance of our convertible preferred stock, the issuance of the 2018 Notes and net proceeds from our IPO. In connection with our IPO in 2018, we sold an aggregate of 20,700,000 shares of our common stock (inclusive of 2,700,000 shares of common stock pursuant to the over-allotment option granted to the underwriters) at a price of \$18.00 per share and received approximately \$343.3 million in net proceeds. In November 2019, we entered into a sales agreement with Cowen and Company, LLC (Cowen) under which we may from time to time issue and sell shares of our common stock through Cowen in at-the-market (ATM) offerings for an aggregate offering price of up to \$250.0 million. From November 2019 to December 31, 2019, we sold an aggregate of 1,965,082 shares of common stock in ATM offerings resulting in net proceeds of \$54.2 million, after deducting commissions and offering costs of \$1.6 million.

### Capital Resources

Our primary use of cash is to fund construction projects for our manufacturing facility and operating expenses, which consist primarily of clinical manufacturing and research and development expenditures related to UCART19, ALLO-501, ALLO-501A and ALLO-715; 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, and when, we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we are unable to raise capital when needed, we will need to delay, reduce or terminate planned activities to reduce costs. Doing so will likely harm our ability to execute our business plans.

### Cash Flows

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

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	\$ (137,350)	\$ (44,653)
Investing activities	164,084	(632,798)
Financing activities	58,960	771,182
Net increase in cash, cash equivalents and restricted cash	<u>\$ 85,694</u>	<u>\$ 93,731</u>

### Operating Activities

During the year ended December 31, 2019, cash used in operating activities of \$137.4 million was attributable to a net loss of \$184.6 million, substantially offset by non-cash charges of \$54.1 million and a net change of \$6.9 million in our net operating assets and liabilities. The non-cash charges consisted primarily of stock-based compensation of \$46.1 million, non-cash rent expense of \$6.8 million and depreciation and amortization of \$4.4 million, offset by net amortization and accretion on investment securities of \$3.6 million. The net change in operating assets and liabilities was primarily due to a \$6.4 million increase in accrued and other current liabilities, offset by an increase in prepaid expenses and other current assets of \$5.4 million, an increase in other long-term assets of \$4.4 million and a decrease in other-long term liabilities of \$2.4 million.

During the year ended December 31, 2018, cash used in operating activities of \$44.7 million was attributable to a net loss of \$211.5 million, substantially offset by non-cash charges of \$154.8 million and a net change of \$12.1 million in our net operating assets and liabilities. The non-cash charges 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 \$21.2 million and \$18.6 million of stock-based compensation. The net change in operating assets and liabilities was primarily due to a \$12.1 million increase in accruals and other liabilities driven by increased professional fees and an \$8.8 million increase in accounts payable resulting from the timing of payments made to our collaboration partners and Pfizer accrued services. This was partially offset by a \$8.6 million increase in prepaid expenses and other current assets and a \$0.2 million increase in other long-term assets.

### **Investing Activities**

During the year ended December 31, 2019, net cash provided by investing activities of \$164.1 million was related to proceeds from investment maturities of \$472.6 million, offset by cash used for investment purchases of \$252.6 million, cash used in purchases of property and equipment of \$50.8 million and cash used in connection with our investment in Notch's series seed convertible preferred stock of \$5.1 million, inclusive of transaction costs.

During the year ended December 31, 2018, cash used by investing activities of \$632.8 million was related to the purchase of investments of \$649.3 million, cash transaction costs of \$2.1 million incurred in the asset acquisition from Pfizer and the purchase of property and equipment of \$3.2 million. This was offset by cash inflows from maturities of investments of \$19.2 million and cash inflows from sales of investments of \$2.6 million.

### **Financing Activities**

During the year ended December 31, 2019, net cash provided by financing activities of \$59.0 million was related to net proceeds from the issuance of common stock in ATM offerings of \$54.2 million, proceeds from the issuance of common stock upon the exercise of stock options of \$3.0 million and proceeds from the employee stock purchase plan of \$1.8 million.

During the year ended December 31, 2018, cash provided by financing activities of \$771.2 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 from the issuance of the 2018 Notes, \$343.7 million in net proceeds from our IPO and \$11.4 million from the issuance of common stock in connection with stock option exercises.

## **Contractual Obligations and Commitments**

The following table summarizes our commitments and contractual obligations as of December 31, 2019

	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>2020</b>	<b>2021-2023</b>	<b>2024-2026</b>	<b>2027 and After</b>
(in thousands)					
<b>Contractual Obligations:</b>					
Operating lease obligations <sup>1</sup>	\$ 93,312	\$ 5,662	\$ 23,786	\$ 25,650	\$ 38,214
<b>Total</b>	<b>\$ 93,312</b>	<b>\$ 5,662</b>	<b>\$ 23,786</b>	<b>\$ 25,650</b>	<b>\$ 38,214</b>

<sup>1</sup> In August 2018, we entered into an operating lease agreement for our headquarters in South San Francisco. The lease term is 127 months beginning August 2018 through February 2029. In October 2018, we entered into an operating lease agreement for additional office and laboratory space in South San Francisco near our headquarters. The lease has a term of ten years and four months commencing on November 1, 2018. In December 2018, we entered into an operating lease agreement for office space in New York, and another operating lease agreement for office space in Los Angeles. The lease terms are 79 months and 36 months, respectively, with the leases commencing on December 1, 2018 and December 19, 2018, respectively. In February 2019, we entered into a lease agreement for manufacturing space in Newark, California. The lease term is for 188 months beginning October 2019.

### **Commitments**

Our commitments primarily consist of obligations under our agreements with Pfizer, Collectis, Servier and Notch. Under these agreements we are required to make milestone payments upon successful completion of certain regulatory and sales milestones on a target-by-target and country-by-country basis. The payment obligations under the license agreements are

contingent upon future events such as our achievement of specified development, regulatory and commercial milestones and we will be required to make development milestone payments and royalty payments in connection with the sale of products developed under these agreements. As of December 31, 2019, we were unable to estimate the timing or likelihood of achieving the milestones or making future product sales.

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 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, research and development expenses, stock-based compensation and leases have the most significant impact on our financial statements. Therefore, we consider these to be our critical accounting policies and estimates.

##### ***Accrued Research and Development Costs***

We accrue liabilities for estimated costs of research and development activities conducted by our collaboration partners and third-party service providers, which include the conduct of preclinical and clinical studies, and contract manufacturing activities. We recorded 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 the accrued and other current liabilities on the balance sheets and within research and development expense on the statements of operations and comprehensive loss.

We accrue for these costs based on factors such as estimates of the work completed and budget provided and in accordance with agreements established with our collaboration partners and third-party service providers. We make significant judgments and estimates in determining the accrued liabilities balance in each reporting period. As actual costs become known, we adjust its accrued liabilities. We have not experienced any material differences between accrued costs and actual costs incurred since our inception.

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

We expense research and development costs as incurred. Acquired intangible assets are expensed as research and development costs if, at the time of payment, the technology is under development; is not approved by the FDA or other regulatory agencies for marketing; has not reached technical feasibility; or otherwise has no foreseeable alternative future use.

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 our behalf. Costs associated with co-development activities performed under the various license and collaboration agreements, including milestones achieved, are included in research and development expenses.

### **Stock-Based Compensation**

We recognize compensation costs related to stock-based awards granted to employees and directors, including stock options, based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value, and the resulting stock-based compensation, using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is generally recognized on a straight-line basis over the requisite service period, which is generally the vesting period of the respective awards.

The Black-Scholes option-pricing model requires the use of subjective assumptions to determine the fair value of stock-based awards. These assumptions include:

- *Fair value of common stock*—For grants before October 2018 when we were private and there was no public market for our common stock, the fair value of our common stock underlying share-based awards was estimated on each grant date by our board of directors. In order to determine the fair value of our common stock underlying option grants, our board of directors considered, among other things, valuations of our common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. For all grants subsequent to our IPO in October 2018, the fair value of common stock was determined by taking the closing price per share of common stock per Nasdaq.
- *Expected term*— The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for option grants is determined using the simplified method. The simplified method deems the term to be the average of the time-to-vesting and the contractual life of the stock-based awards.
- *Expected volatility*— We use an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as we do not have sufficient trading history for our common stock. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.
- *Risk-free interest rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of option.
- *Expected dividend*—We have never paid dividends on its common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

For the years ended December 31, 2019 and 2018, stock-based compensation was \$46.1 million and \$18.6 million respectively. As of December 31, 2019 and 2018, we had \$148.6 million and \$87.4 million of total unrecognized stock-based compensation relating to options, restricted stock units and founders stock.

### **Leases**

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*. For our long-term operating leases, we recognized right-of-use assets and lease liabilities on our balance sheet. The lease liabilities are determined as the present value of future lease payments using an estimated rate of interest that we would have to pay to borrow equivalent funds on a collateralized basis at the lease commencement date. The right-of-use assets are based on the liability adjusted for any prepaid or deferred rent. For each lease, 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.

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

### **Recent Accounting Pronouncements**



Please refer to Note 2 to our financial statements for a discussion of new accounting standards updates that may impact us.

**Item 7A. Quantitative and Qualitative Disclosures About Market Risk.**

***Interest Rate Risk***

Our cash, cash equivalents and investments of \$588.9 million as of December 31, 2019, consist of bank deposits, money market funds and available-for-sale securities. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant for us. A 10% change in the interest rates in effect on December 31, 2019 would not have had a material effect on the fair market value of our cash equivalents and available-for-sale securities.

***Foreign Currency Exchange Rate Risk***

Our collaboration agreement with Servier requires collaboration payments for shared clinical development costs to be paid in euros, and thus we face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars. Due to the uncertain timing of expected payments in foreign currencies, we do not utilize any forward exchange contracts. All foreign transactions settle on the applicable spot exchange basis at the time such payments are made. An adverse movement in foreign exchange rates could have an effect on payments due and made to our collaboration partner as well as other foreign suppliers and for license agreements. A 10% change in the applicable foreign exchange rates during the periods presented would not have had a material effect on our consolidated financial statements. As of December 31, 2019, we had \$2.4 million of liabilities denominated in foreign currency.

**Item 8. Financial Statements and Supplementary Data.**

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For the year ended December 31, 2019 and 2018

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## Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of  
Allogene Therapeutics, Inc.

### Opinion on the Financial Statements

We have audited the accompanying balance sheets of Allogene Therapeutics, Inc. (the Company) as of December 31, 2019 and 2018, the related statements of operations and comprehensive loss, statements of convertible preferred stock and stockholders' equity (deficit) and cash flows for each of the years ended December 31, 2019 and 2018 and the period from November 30, 2017 (inception) to December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the years ended December 31, 2019 and 2018 and the period from November 30, 2017 (inception) to December 31, 2017, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) and our report dated February 27, 2020 expressed an unqualified opinion thereon.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

### Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

### Accrued Research and Development Costs

*Description of the Matter* As discussed in Note 1 liabilities are recorded for estimated unpaid costs of research and development activities conducted by the Company and its collaboration partners and third-party service providers, which include the conduct of preclinical and clinical studies, and contract manufacturing activities. Total research and development expenses were \$144.5 million during the year ended December 31, 2019 and include the estimated costs of accrued research and development activities for services provided but not yet invoiced. The accrual for these costs is determined after consideration of several factors, including budgets and estimates of the work completed in accordance with agreements established with the Company's collaboration partners and third-party service providers. Auditing accrued research and development costs was complex due to significant judgments and estimates made by management in determining the required accruals.

*How We Addressed the Matter in Our Audit* We obtained an understanding, evaluated the design, and tested the operating effectiveness of relevant controls over the Company's determination of accrued research and development costs, including controls over the determination of significant assumptions and the completeness and accuracy of the data used in determining accrued costs.

Our audit procedures included, among others, examining, on a test basis, evidence regarding the estimated accrued amounts through comparison of expenses incurred to budgeted amounts and to expenses incurred in prior periods and obtaining an understanding of the reasons for changes. We verified that accrued amounts were in accordance with key terms and conditions through review of the underlying agreements with the Company's collaboration partners and third-party service providers. We verified expenses incurred by obtaining confirmation from the Company's collaboration partner and further validated accrued amounts based on information provided by third-party service providers.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.  
San Jose, California  
February 27, 2020

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

	December 31, 2019	December 31, 2018
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 175,126	\$ 92,432
Short-term investments	355,407	366,952
Prepaid expenses and other current assets	14,043	8,598
Total current assets	544,576	467,982
Long-term investments	58,322	261,966
Operating lease right-of-use asset	44,495	33,015
Property and equipment, net	56,449	8,595
Intangible assets, net	151	754
Restricted cash	4,299	1,299
Other long-term assets	4,618	244
Equity method investment	4,892	—
Total assets	\$ 717,802	\$ 773,855
<b>Liabilities, convertible preferred stock and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 9,250	\$ 12,338
Accrued and other current liabilities	23,829	17,121
Total current liabilities	33,079	29,459
Lease liability, noncurrent	51,349	34,456
Other long-term liabilities	4,351	6,776
Total liabilities	88,779	70,691
Commitments and Contingencies (Notes 6, 7 and 8)		
Stockholders' equity:		
Preferred stock, \$0.001 par value: 10,000,000 authorized as of December 31, 2019 and December 31, 2018, respectively; no shares were issued and outstanding as of December 31, 2019 and December 31, 2018	—	—
Common stock, \$0.001 par value: 200,000,000 authorized as of December 31, 2019 and December 31, 2018; 124,267,358 and 121,482,671 shares issued and outstanding as of December 31, 2019 and December 31, 2018, respectively	124	121
Additional paid-in capital	1,023,876	914,265
Accumulated deficit	(396,122)	(211,528)
Accumulated other comprehensive income	1,145	306
Total stockholders' equity	629,023	703,164
<b>Total liabilities and stockholders' equity</b>	<b>\$ 717,802</b>	<b>\$ 773,855</b>

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

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

	<b>Years Ended December 31,</b>		<b>Period from</b>
	<b>2019</b>	<b>2018</b>	<b>November 30, 2017</b>
			<b>(Inception) to</b>
			<b>December 31,</b>
			<b>2017</b>
Operating expenses:			
Research and development	\$ 144,535	\$ 151,860	\$ —
General and administrative	57,473	40,982	2
Total operating expenses	202,008	192,842	2
Loss from operations	(202,008)	(192,842)	(2)
Other income (expense), net:			
Change in fair value of convertible note payable	—	(21,211)	—
Interest expense	—	(3,358)	—
Interest and other income, net	17,351	5,789	—
Other expenses	(268)	—	—
Total other income (expense), net	17,083	(18,780)	—
Loss before income taxes	(184,925)	(211,622)	(2)
Benefit from income taxes	331	117	—
Net loss	(184,594)	(211,505)	(2)
Other comprehensive income:			
Net unrealized gain on available-for-sale investments, net of tax	839	306	—
Net comprehensive loss	\$ (183,755)	\$ (211,199)	\$ (2)
Net loss per share, basic and diluted	\$ (1.83)	\$ (7.31)	\$ 0.00
Weighted-average number of shares used in computing net loss per share, basic and diluted	101,061,149	28,948,386	26,249,993

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

**ALLOGENE THERAPEUTICS, INC.**  
**Statements of Convertible Preferred Stock and Stockholders' Equity (Deficit)**  
(In thousands, except share and per share data)

	Series A Convertible Preferred Stock		Subscriptions Receivables from Preferred Stockholders	Common Stock		Notes Receivable from Common Stockholders	Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity (Deficit)
	Shares	Amount		Shares	Amount					
<b>Balance — November 30, 2017 (Inception)</b>	—	\$ —	\$ —	—	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Issuance of common stock	—	—	—	26,249,993	26	—	—	(21)	—	5
Notes receivable from common stockholders	—	—	—	—	—	(5)	—	—	—	(5)
Net loss and comprehensive loss	—	—	—	—	—	—	—	(2)	—	(2)
<b>Balance — December 31, 2017</b>	—	—	—	26,249,993	26	(5)	—	(23)	—	(2)
Issuance of Series A convertible preferred shares at \$35.06 per share, net of issuance costs of \$635	7,557,990	264,365	—	—	—	—	—	—	—	—
Issuance of Series A-1 convertible preferred shares at \$35.06 per share in connection with asset acquisition	3,187,772	111,770	—	—	—	—	—	—	—	—
Issuance of Series A-1 convertible preferred shares at \$35.06 per share, net of issuance costs of \$84	998,225	34,917	—	—	—	—	—	—	—	—
Proceeds received from common stockholders for issuance of founders' stock at inception	—	—	—	—	—	5	—	—	—	5
Subscriptions receivable from preferred stockholders	—	—	(150,000)	—	—	—	—	—	—	(150,000)
Proceeds received from preferred stockholders	—	—	150,000	—	—	—	—	—	—	150,000
Issuance of common stock for early exercise of stock options	—	—	—	5,020,580	5	—	—	—	—	5
Issuance of common stock upon initial public offering, net of issuance costs of \$29,272	—	—	—	20,700,000	21	—	343,308	—	—	343,329
Conversion of Series A convertible preferred stock	(11,743,987)	(411,052)	—	61,655,922	62	—	410,990	—	—	411,052
Issuance of common stock upon conversion of convertible notes	—	—	—	7,856,176	7	—	141,403	—	—	141,410
Adjustment for fractional shares from forward stock split	—	—	—	—	—	—	(2)	—	—	(2)
Stock-based compensation	—	—	—	—	—	—	18,566	—	—	18,566
Net loss	—	—	—	—	—	—	—	(211,505)	—	(211,505)
Net unrealized gain on available-for-sale investments	—	—	—	—	—	—	—	—	306	306
<b>Balance — December 31, 2018</b>	—	—	—	121,482,671	121	—	914,265	(211,528)	306	703,164
Issuance of common stock upon exercise of stock options and vesting of RSU's	—	—	—	711,623	1	—	2,958	—	—	2,959
Vesting of early exercised common stock	—	—	—	—	—	—	4,590	—	—	4,590
Stock-based compensation	—	—	—	—	—	—	46,063	—	—	46,063
Employee stock purchase plan	—	—	—	107,982	—	—	1,783	—	—	1,783
Issuance of common stock from public offering, net of commissions and offering costs of \$1.6 million	—	—	—	1,965,082	2	—	54,217	—	—	54,219
Net Loss	—	—	—	—	—	—	—	(184,594)	—	(184,594)
Net unrealized gain on available-for-sale investments	—	—	—	—	—	—	—	—	839	839
<b>Balance — December 31, 2019</b>	—	\$ —	\$ —	124,267,358	\$ 124	\$ —	\$ 1,023,876	\$ (396,122)	\$ 1,145	\$ 629,023

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

**ALLOGENE THERAPEUTICS, INC.**  
**Statements of Cash Flows**  
**(in thousands)**

	Year Ended December 31,		Period from November 30, 2017 (Inception) to December 31, 2017
	2019	2018	
<b>Cash flows from operating activities:</b>			
Net loss	\$ (184,594)	\$ (211,505)	\$ (2)
Adjustments to reconcile net loss to net cash (used in) operating activities:			
Acquired in-process research and development	—	109,436	—
Stock-based compensation	46,063	18,566	—
Amortization of other intangible assets acquired	603	452	—
Depreciation and amortization	4,424	1,048	—
Net amortization/accretion on investment securities	(3,596)	(1,036)	—
Non-cash rent expense	6,777	1,832	—
Change in fair value of convertible notes payable	—	21,211	—
Debt issuance costs on convertible notes payable	—	3,358	—
Income tax benefit	(331)	(117)	—
Share of losses from equity method investments	182	—	—
Other	—	6	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(5,445)	(8,598)	—
Other long-term assets	(4,374)	(244)	—
Accounts payable	(985)	8,800	—
Accrued and other current liabilities	6,351	12,138	2
Other long-term liabilities	(2,425)	—	—
Net cash used in operating activities	(137,350)	(44,653)	—
<b>Cash flows from investing activities:</b>			
Purchases of property and equipment	(50,791)	(3,234)	—
Purchase of stock in equity method investment	(5,075)	—	—
Proceeds from sales of investments	—	2,606	—
Proceeds from maturities of investments	472,578	19,235	—
Purchase of investments	(252,628)	(649,307)	—
Cash paid for acquisition of assets	—	(2,098)	—
Net cash provided by (used in) investing activities	164,084	(632,798)	—
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	299,281	—
Proceeds from issuance of convertible notes, net of issuance costs	—	116,842	—
Proceeds from early exercise of stock options	—	11,370	—
Proceeds from issuance of common stock, net of commissions and issuance costs	54,219	343,689	—
Proceeds from issuance of common stock and upon exercise of stock options	2,958	—	—
Proceeds from issuance of common stock under the employee stock purchase plan	1,783	—	—
Net cash provided by financing activities	58,960	771,182	—
Net increase in cash, cash equivalents and restricted cash	85,694	93,731	—
Cash, cash equivalents and restricted cash — beginning of period	93,731	—	—
Cash, cash equivalents and restricted cash — end of period	\$ 179,425	\$ 93,731	\$ —
<b>Non-cash operating, investing and financing activities:</b>			
Common stock issued on conversion of convertible preferred stock	\$ —	\$ 411,052	\$ —
Common stock issued on conversion of convertible notes payable	\$ —	\$ 141,410	\$ —
Series A-1 convertible preferred stock issued in asset acquisition	\$ —	\$ 111,770	\$ —
PP&E and other assets acquired in asset acquisition	\$ —	\$ 111,770	\$ —
Right-of-use asset obtained in exchange for lease liability	\$ 13,827	\$ 33,015	\$ —
Property and equipment purchases in accounts payable and accrued liabilities	\$ 4,668	\$ 3,182	\$ —
Deferred offering costs included in accounts payable and accrued and other current liabilities	\$ 135	\$ 356	\$ —
<b>Supplemental disclosure:</b>			
Cash paid for amounts included in the measurement of lease liabilities	\$ (3,563)	\$ (31)	\$ —
Cash received for amounts related to tenant improvement allowances from lessors	\$ 4,473	\$ —	\$ —

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



**ALLOGENE THERAPEUTICS, INC.**  
**Notes to Financial Statements**

**Note 1. Description of Business and Summary of Significant Accounting Policies**

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 11).

**Public Offerings**

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 \$343.3 million in net proceeds, after deducting underwriting discounts and commissions of \$26.1 million and offering expenses of \$3.2 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 10) were automatically converted into 7,856,176 shares of common stock. Following the IPO, there were no shares of convertible preferred stock or preferred stock outstanding.

In November 2019, the Company entered into a sales agreement with Cowen and Company, LLC (Cowen), under which the Company may from time to time issue and sell shares of its common stock through Cowen in at-the-market (ATM) offerings for an aggregate offering price of up to \$250.0 million. The aggregate compensation payable to Cowen as the Company's sales agent equals up to 3.0% of the gross sales price of the shares sold through it pursuant to the sales agreement. Beginning November 2019 and through the year ended December 31, 2019, the Company sold an aggregate of 1,965,082 shares of common stock in ATM offerings resulting in net proceeds of \$54.2 million, after deducting commissions and offering costs of \$1.6 million.

**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. Upon the completion of the IPO in October 2018, \$3.2 million of deferred offering costs were reclassified to additional paid in capital. Offering costs, including legal, accounting and filing fees related to the ATM offerings were incurred. Upon the issuance and sale of common stock in ATM offerings in November 2019, \$0.5 million of deferred offering costs were reclassified to additional paid in capital. There were no deferred offering costs capitalized as of December 31, 2019 and 2018.

**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 financial statements have been retrospectively adjusted to reflect the effect of the Forward Stock Split for all periods presented.

**Need for Additional Capital**

The Company has sustained operating losses and expects to continue to generate operating losses for the foreseeable future. The Company's ultimate success depends on the outcome of its research and development activities as well as the ability

to commercialize the Company's product candidates. The Company had cash and cash equivalents and investments of \$588.9 million as of December 31, 2019. Since inception through December 31, 2019, the Company has incurred cumulative net losses of \$396.1 million. Management expects to incur additional losses in the future to fund its operations and conduct product research and development and recognizes the need to raise additional capital to fully implement its business plan.

The Company intends to raise 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 at least the next 12 months from the date the Company's Annual Report on Form 10-K is filed with the Securities and Exchange Commission (SEC).

#### ***Basis of Presentation***

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (GAAP).

#### ***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions made in the accompanying financial statements include but are not limited to the fair value of common stock, the fair value of stock options, the fair value of investments, the fair value of convertible notes payable upon conversion, income tax uncertainties, and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances change. Actual results could differ from those estimates.

#### ***Concentration of Credit and other Risks and Uncertainties***

Financial instruments, which potentially subject the Company to significant concentrations of credit risk, consist primarily of cash and cash equivalents and investments. The primary objectives for the Company's investment portfolio are the preservation of capital and the maintenance of liquidity. The Company does not enter into any investment transaction for trading or speculative purposes.

The Company's investment policy limits investments to certain types of instruments such as certificates of deposit, commercial paper, money market instruments, obligations issued by the U.S. government and U.S. government agencies as well as corporate debt securities, and places restrictions on maturities and concentration by type and issuer. The Company maintains cash balances in excess of amounts insured by the FDIC and concentrated within a limited number of financial institutions. The accounts are monitored by management and management believes that the financial institutions are financially sound, and, accordingly, minimal credit risk exists with respect to these financial institutions. As of December 31, 2019 and 2018, the Company has not experienced any credit losses in such accounts or investments.

The Company is subject to a number of risks common for early-stage biopharmaceutical companies including, but not limited to, dependency on the clinical and commercial success of its product candidates, ability to obtain regulatory approval of its product candidates, the need for substantial additional financing to achieve its goals, uncertainty of broad adoption of its approved products, if any, by physicians and patients, significant competition and untested manufacturing capabilities.

#### ***Segments***

Operating segments are defined as components of an entity for which separate financial information is available and that is regularly reviewed by the Chief Operating Decision Maker (CODM) in deciding how to allocate resources to an individual segment and in assessing performance. The Company's CODM is its Chief Executive Officer. The Company has determined it operates in a single operating segment and has one reportable segment.

#### ***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 letters of credit under separate lease agreements which have been collateralized by restricted cash. This cash is classified as long-term restricted cash on the accompanying balance sheet based on the terms of the underlying leases.

### ***Investments***

Investments are available-for-sale and are carried at estimated fair value. The Company's valuations of marketable securities are generally derived from independent pricing services based upon quoted prices in active markets for similar securities, with prices adjusted for yield and number of days to maturity, or based on industry models using data inputs, such as interest rates and prices that can be directly observed or corroborated in active markets. Management determines the appropriate classification of its investments in debt securities at the time of purchase and at the end of each reporting period. 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 income. 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.

### ***Property and Equipment, Net***

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed on a straight-line basis over the estimated useful lives of the related assets, generally three to seven years. Maintenance and repairs are charged to operations as incurred. Upon sale or retirement of assets, the cost and related accumulated depreciation are removed from the balance sheet and the resulting gain or loss is reflected in other expense.

The Company has determined the estimated life of assets to be as follows:

Laboratory equipment	5 years
Computer equipment and purchased software	3 - 5 years
Fixtures and furniture	7 years
Leasehold improvements	Shorter of lease term or useful life

### **Leases**

The Company early adopted Accounting Standards Update (ASU) No. 2016-2, *Leases* on January 1, 2018. For its long-term operating leases, the Company recognizes a right-of-use asset and a lease liability on its balance sheets. The lease liability is determined as the present value of future lease payments using an estimated rate of interest that the Company would 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 non-lease components for its long-term real-estate leases.

### **Equity Method Investments**

The Company uses the equity method of accounting for equity investments in companies if the investment provides the ability to exercise significant influence, but not control, over operating and financial policies of the investee. The Company's proportionate share of the net income or loss of these companies is included in other expenses in the statement of operations. Judgment regarding the level of influence over each equity method investment includes considering key factors such as our ownership interest, representation on the board of directors, participation in policy-making decisions and material purchase and sale transactions.

The Company evaluates equity method investments for impairment whenever events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable. Factors considered when reviewing an equity method investment for impairment include the length of time (duration) and the extent (severity) to which the fair value of the equity method investment has been less than cost, the investee's financial condition and near-term prospects and the intent and ability to hold the investment for a period of time sufficient to allow for anticipated recovery. An impairment that is other-than-temporary is recognized in the period identified.

### **Variable Interest Entities**

For entities in which the Company has variable interests, the Company focuses on identifying if one of the entities is the primary beneficiary through having the power to direct the activities that most significantly impact the variable interest entity's economic performance and having the obligation to absorb losses or the right to receive benefits from the variable interest entity. If the Company is the primary beneficiary of a variable interest entity, the assets, liabilities, and results of operations of the variable interest entity will be included in the Company's financial statements. For the year ended December 31, 2019, the Company did not consolidate any variable interest entities because the Company determined that it was not the primary beneficiary.

### **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 the balance sheets and within research and development expenses on the statements of operations and comprehensive loss.

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 at the end of 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.

### ***Income Taxes***

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Management makes an assessment of the likelihood that the resulting deferred tax assets will be realized. A valuation allowance is provided when it is more likely than not that some portion or all of a deferred tax asset will not be realized. Due to the Company's historical operating performance and net losses, the net deferred tax assets have been fully offset by a valuation allowance.

The Company recognizes uncertain income tax positions at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Changes in recognition or measurement are reflected in the period in which judgment occurs. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of the provision for income taxes.

### ***Stock-Based Compensation***

The Company measures its stock-based awards granted to employees, consultants and directors based on the estimated fair values of the awards and recognizes the compensation over the requisite service period. The Company uses the Black-Scholes option-pricing model to estimate the fair value of its stock-based awards. Stock-based compensation is recognized using the straight-line method. As the stock compensation expense is based on awards ultimately expected to vest, it is reduced by forfeitures. The Company accounts for forfeitures as they occur.

### ***Net Loss Per Share***

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share since the effects of potentially dilutive securities are antidilutive. Shares of common stock subject to repurchase are excluded from the weighted-average shares.

### ***Comprehensive Loss***

Comprehensive loss includes net loss and certain changes in stockholders' equity (deficit) that are excluded from net loss. For the years ended December 31, 2019 and 2018 this was comprised of unrealized gains and losses, net of tax, on the Company's investments. For the period from November 30, 2017 (inception) to December 31, 2017, comprehensive net loss was equal to net loss.

### ***Definite-Lived Intangible Assets***

Identifiable intangible assets consist of in-process research and development and workforce associated with the Pfizer asset acquisition. Intangible assets with finite lives are amortized over their estimated useful lives on a straight-line basis, generally two years. Acquired in-process research and development intangible assets with no alternative future use are charged to research and development expense when acquired. The straight-line method of amortization represents the Company's best estimate of the distribution of the economic value of the identifiable intangible assets. Intangible assets are carried at cost less accumulated amortization. Amortization of intangible assets is included in research and development expenses.

### ***Impairment of Long-Lived Assets***

Long-lived assets are reviewed annually for impairment or whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability is measured by comparison of the carrying amount of an asset group to the future net undiscounted cash flows that the assets are expected to generate. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the projected discounted future net cash flows arising from the asset. There were impairment losses related to equipment disposals of \$0.2 million and zero for the years ended December 31, 2019 and 2018, respectively.

## **Research and Development Expenses**

Research and development costs are expensed as incurred and 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. Research and development expenses also include costs incurred for internal and sponsored collaborative research and development activities. Costs associated with co-development activities performed under the various license and collaboration agreements are included in research and development expenses.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are capitalized and then expensed as the related goods are delivered or the services are performed.

Research and development expenses for the year ended December 31, 2018 primarily consisted of acquired intangible assets pursuant to the Asset Contribution Agreement with Pfizer (see Note 6) 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 year ended December 31, 2018, the Company recognized expense of \$109.4 million related to the acquired intangible in-process research and development.

## **Note 2. Recent Accounting Guidance**

### **Recently Adopted Accounting Pronouncements**

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 have not 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. As a result, the accounting for share-based payments to nonemployee consultants is consistent with employees.

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 ending cash balances within the statements of cash flows. The adoption had no other material impacts to the 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 statements 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. Early adoption is permitted. The standard requires a modified-retrospective transition method and

provides for certain practical expedients. The Company early adopted the new lease standard on July 1, 2018 with the adoption reflected as of January 1, 2018 in accordance with ASU No. 2018-11, *Leases (Topic 842) – Targeted Improvements*. There were no lease arrangements prior to August 2018 and consequently, the adoption of the standard did not have any impact on periods prior to August 2018.

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

### **Recent Accounting Pronouncements Not Yet Adopted**

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments* and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04, ASU 2019-05, and ASU 2019-11. The standard requires measurement and recognition of expected credit losses for financial assets by requiring an allowance to be recorded as an offset to the amortized cost of such assets. For available-for-sale debt securities, expected credit losses should be estimated when the fair value of the debt securities is below their associated amortized costs. The standard will become effective for the Company in the first quarter of 2020, with early adoption permitted beginning the first quarter of 2019. The modified retrospective approach should be applied upon adoption of this new guidance. The Company's financial instruments that are in the scope of ASU 2016-13 include but not limited to trade receivables and available-for-sale debt securities. The Company will adopt this standard on January 1, 2020 and does not anticipate this amendment to have a material impact on the financial statements.

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

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which clarifies that certain transactions between participants in a collaborative arrangement should be accounted for under ASC 606 when the counterparty is a customer. In addition, Topic 808 precludes an entity from presenting consideration from a transaction in a collaborative arrangement as revenue from contracts with customers if the counterparty is not a customer for that transaction. The Company will adopt this standard on January 1, 2020 and does not anticipate this amendment to have a material impact on the financial statements.

In December 2019, the FASB issued Accounting Standard Update No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes (ASU 2019-12)*, which simplifies the accounting for income taxes, eliminates certain exceptions within ASC 740, *Income Taxes*, and clarifies certain aspects of the current guidance to promote consistency among reporting entities. This guidance will be effective for the Company in the first quarter of 2021 on a prospective basis, and early adoption is permitted. The Company is currently evaluating the impact of the new guidance on the financial statements.

In January 2020, the FASB issues Accounting Standard Update No. 2020-01, *Investments – Equity Securities (Topic 321), Investments – Equity Method and Joint Ventures (Topic 323)*, which clarifies the interactions between topics 321 and 323 in applying or discontinuing the equity method of accounting for investments. This guidance will be effective for the Company in the first quarter of 2021, and early adoption is permitted. The Company is currently evaluating the impact of the new guidance on the financial statements.

### **Note 3. Fair Value Measurements**

The Company follows authoritative accounting guidance, which among other things, defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is an exit price, representing the amount that would be received

to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability.

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, except for investments in U.S. treasury securities which are classified as Level 1.

There were no Level 3 assets or liabilities at December 31, 2019 or 2018.

Financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of December 31, 2019 are presented in the following table:

	December 31, 2019			
	Level 1	Level 2	Level 3	Fair Value
	(in thousands)			
<b>Financial Assets:</b>				
Money market funds <sup>1</sup>	\$ 122,900	\$ —	\$ —	\$ 122,900
Corporate bonds	—	205,011	—	205,011
U.S. treasury securities	181,894	—	—	181,894
U.S. agency securities	—	25,824	—	25,824
Certificates of deposit	—	1,000	—	1,000
<b>Total financial assets</b>	<b>\$ 304,794</b>	<b>\$ 231,835</b>	<b>\$ —</b>	<b>\$ 536,629</b>

<sup>1</sup> Included within cash and cash equivalents on the Company's balance sheet

Financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements by major security type as of December 31, 2018 are presented in the following table:

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

<sup>1</sup> Included within cash and cash equivalents on the Company's balance sheet

The carrying amounts of accounts payable and accrued liabilities approximate their fair values due to their short-term maturities. The Company's Level 2 securities are valued using third-party pricing sources. The pricing services utilize industry standard valuation models, including both income and market-based approaches, for which all significant inputs are observable, either directly or indirectly.

There were no transfers of assets between the fair value measurement levels during the years ended December 31, 2019 or 2018.

#### Note 4. Investments



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The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of December 31, 2019 are presented in the following table:

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
(in thousands)				
Money market funds	\$ 122,900	\$ —	\$ —	\$ 122,900
Corporate bonds	204,144	871	(4)	205,011
U.S. treasury securities	181,340	557	(3)	181,894
U.S. agency securities	25,658	167	(1)	25,824
Certificates of deposit	1,000	—	—	1,000
Total cash equivalents and investments	\$ 535,042	\$ 1,595	\$ (8)	\$ 536,629

Classified as:

Cash equivalents	\$ 122,900
Short-term investments	355,407
Long-term investments	58,322
Total cash equivalents, and investments	\$ 536,629

The fair value and amortized cost of cash equivalents and available-for-sale securities by major security type as of December 31, 2018 are presented in the following table:

	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
(in thousands)				
Money market funds	\$ 61,023	\$ —	\$ —	\$ 61,023
Commercial Paper	4,917	—	—	4,917
Corporate bonds	244,136	220	(280)	244,076
U.S. treasury securities	341,696	342	(37)	342,001
U.S. agency securities	61,937	181	(3)	62,115
Total cash equivalents and investments	\$ 713,709	\$ 743	\$ (320)	\$ 714,132

Classified as:

Cash equivalents	\$ 85,214
Short-term investments	366,952
Long-term investments	261,966
Total cash equivalents, and investments	\$ 714,132

The fair values of available-for-sale debt investments by contractual maturity as of December 31, 2019 and 2018 were as follows:

	December 31,	
	2019	2018
	(in thousands)	
Due in 1 year or less	\$ 355,407	\$ 375,625
Due in 1 - 2 years	58,322	240,614
Due in 3 years	—	36,870
Instruments not due at a single maturity date	122,900	61,023
Total cash equivalents and investments	<u>\$ 536,629</u>	<u>\$ 714,132</u>

As of December 31, 2019 and 2018, the remaining contractual maturities of available-for-sale securities were less than two years and three years, respectively. There have been no significant realized losses on available-for-sale securities for the years ended December 31, 2019 and 2018. Based on the Company's review of its available-for-sale securities, the Company believes it had no other-than-temporary impairments on these securities as of December 31, 2019 and 2018, because the Company does not intend to sell these securities nor does the Company believe that it will be required to sell these securities before the recovery of their amortized cost basis. Gross realized gains and gross realized losses were immaterial for the years ended December 31, 2019 and 2018.

#### Note 5. Balance Sheet Components

##### *Prepaid Expenses and Other Current Assets*

	December 31,	
	2019	2018
	(in thousands)	
Prepaid research and development expenses	\$ 6,387	\$ 2,356
Prepaid insurance	2,625	2,376
Accrued interest on short-term marketable securities	2,403	3,108
Other prepaid and current assets	2,628	758
Total prepaid expenses and other current assets	<u>\$ 14,043</u>	<u>\$ 8,598</u>

##### *Property and Equipment, Net*

	December 31,	
	2019	2018
	(in thousands)	
Leasehold improvements	\$ 29,924	\$ 15
Laboratory equipment	13,117	5,534
Construction in progress	12,390	2,703
Computers equipment and purchased software	3,726	1,327
Furniture and fixtures	2,764	64
Total	61,921	9,643
Less: accumulated depreciation	(5,472)	(1,048)
Total property and equipment, net	<u>\$ 56,449</u>	<u>\$ 8,595</u>

Depreciation expense for the years ended December 31, 2019 and 2018 was \$4.6 million and \$1.0 million, respectively. Disposals of property and equipment were \$0.2 million and zero for the years ended December 31, 2019 and 2018, respectively.

**Intangible Assets, Net**

	December 31, 2019		
	Cost	Accumulated Amortization	Carrying Value
	(in thousands)		
Assembled workforce	\$ 1,206	\$ (1,055)	\$ 151

	December 31, 2018		
	Cost	Accumulated Amortization	Carrying Value
	(in thousands)		
Assembled workforce	\$ 1,206	\$ (452)	\$ 754

As of December 31, 2019, the weighted-average remaining amortization period of the assembled workforce was 0.26 years. Amortization expense related to the assembled workforce intangible assets was \$0.6 million and \$0.5 million for the years ended December 31, 2019 and 2018, respectively.

**Accrued Liabilities**

Accrued liabilities consist of the following:

	December 31,	
	2019	2018
	(in thousands)	
Accrued compensation and related benefits	\$ 9,560	\$ 4,111
Accrued research and development expenses	4,833	7,808
Accrued property and equipment	3,575	—
Unvested shares liabilities	2,843	4,590
Other	3,018	612
Total accrued and other current liabilities	\$ 23,829	\$ 17,121

**Note 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 at \$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 11 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 2017-1. 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 on 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 was 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. No milestone payments were made or became due in the years ended December 31, 2019 and 2018. These contingent payments were 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 was 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.

## **Note 7. License and Collaboration 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. In October 2019, the Territory was expanded to all countries in the world. No milestone or royalty payments were made in the years ended December 31, 2019 and 2018.

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 Collectis**

As part of the Pfizer Agreement (see Note 6), Pfizer assigned to the Company a Research Collaboration and License Agreement (the Original Collectis Agreement) with Collectis S.A. (Collectis). On March 8, 2019, the Company entered into a License Agreement (the Collectis Agreement) with Collectis. In connection with the execution of the Collectis Agreement, on March 8, 2019, the Company and Collectis also entered into a letter agreement (the Letter Agreement), pursuant to which the Company and Collectis agreed to terminate the Original Collectis Agreement. The Original Collectis Agreement included a research collaboration to conduct discovery and pre-clinical development activities to generate CAR T cells directed at targets selected by each party, which was completed in June 2018.

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

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

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

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

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

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

Unless earlier terminated in accordance with its terms, the Collectis Agreement will expire on a product-by-product and country-by-country basis, upon expiration of all royalty payment obligations with respect to such licensed product in such

country. The Company has the right to terminate the Collectis Agreement at will upon 60 days' prior written notice, either in its entirety or on a target-by-target basis. Either party may terminate the Collectis Agreement, in its entirety or on a target-by-target basis, upon 90 days' prior written notice in the event of the other party's uncured material breach. The Collectis Agreement may also be terminated by the Company upon written notice at any time in the event that Collectis becomes bankrupt or insolvent or upon written notice within 60 days of a consummation of a change of control of Collectis.

All costs the Company incurred in connection with this agreement were recognized as research and development expenses. For the year ended December 31, 2019, \$5.0 million of costs were incurred related to the achievement of a clinical development milestone under this agreement, which was recognized in research and development expenses in the statement of operations. No clinical development milestones were achieved for the year ended December 31, 2018. For the years ended December 31, 2019 and 2018, zero and \$0.4 million, respectively, of costs have been incurred associated with research services performed by Collectis.

#### ***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 anti-CD19 product candidates and for allogeneic CAR T cell product candidates directed against one additional target. In October 2019, the Company agreed to waive its rights to the one additional target.

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

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

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

The Company is required to make milestone payments to Servier upon successful completion of regulatory and sales milestones. The Servier Agreement provides for aggregate potential payments by the Company to Servier of up to \$137.5 million upon successful completion of various regulatory milestones, and aggregate potential payments by the Company to Servier of up to \$78.0 million upon successful completion of various sales milestones. Similarly, Servier is required to make milestone payments upon successful completion of regulatory and sales milestones for products directed at the Allogene-target covered by the Servier Agreement that achieves such milestones. The total potential payments that Servier is obligated to make to the Company under the Servier Agreement upon successful completion of regulatory and sales milestones are \$42 million and €70.5 million (\$79.1 million), respectively. The foregoing milestones are subject to certain adjustments if the Company obtains rights for certain products outside of the United States upon Servier's election not to pursue such rights.

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

party's respective territory (the Servier Royalty Term) begins upon the first commercial sale of such product in such country and ends after a defined number of years.

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

For the years ended December 31, 2019 and 2018, the Company recorded \$7.3 million and \$4.2 million, respectively, of costs incurred under the cost-sharing terms of the Servier Agreement as research and development expenses. As of December 31, 2019 and 2018, amounts due to Servier of \$2.2 million and \$4.2 million were recorded in accrued and other current liabilities in the accompanying balance sheets.

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

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

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

In connection with the execution of the Notch Agreement, Allogene made an upfront payment to Notch of \$10.0 million in return for a license to access Notch's technology in order to conduct research pursuant to the Notch Agreement. The Company recognized a research and development expense of \$10 million during the year to December 31, 2019 as the license had no foreseeable alternative future use. In addition, Allogene made a \$5.0 million investment in Notch's series seed convertible preferred stock, resulting in Allogene having a 25% ownership interest in Notch's outstanding capital stock on a fully diluted basis immediately following the investment. In connection with this investment, David Chang, M.D., Ph.D., the Company's President, Chief Executive Officer and Board member, was appointed to Notch's board of directors.

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

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

The Company has determined that Notch is a variable interest entity as of December 31, 2019. The Company does not have the power to direct the activities which most significantly affect Notch's economic performance. Accordingly, for the year

ended December 31, 2019, the Company did not consolidate Notch because the Company determined that it was not the primary beneficiary.

#### **Note 8. Leases**

In August 2018, the Company entered into an operating lease agreement for new office and laboratory space which consists of approximately 68,000 square feet located in South San Francisco, California. The lease term is 127 months beginning August 2018 through February 2029 with an option to extend the term for another seven years which is not reasonably assured of exercise. The Company has the right to make tenant improvements, including the addition of laboratory space, with a lease incentive allowance of \$5.1 million. The rent payments began on March 1, 2019 after an abatement period. In connection with the lease, the Company has maintained a letter of credit for the benefit of the landlord in the amount of \$1.0 million. In connection with the lease, the Company recognized an operating lease right-of-use asset of \$23.2 million and \$24.6 million as of December 31, 2019 and 2018, respectively, and an aggregate lease liability of \$30.9 million and \$26.3 million, respectively, on the balance sheet. The remaining lease term is 9 years and 2 months, and the estimated incremental borrowing rate is 8.0%.

In October 2018, the Company entered into an operating lease agreement for new office and laboratory space which consists of approximately 14,943 square feet located in South San Francisco, California. The lease term is 124 months beginning November 2018 through February 2029, with an option to extend the term for another seven years which is not reasonably assured of exercise. The Company has the right to make tenant improvements, including the upgrading of current office and laboratory space with a lease incentive allowance of \$0.8 million. Rent payments began in November 2018. In connection with the lease, the Company has maintained a letter of credit for the benefit of the landlord in the amount of \$0.2 million. In connection with the lease, the Company recognized an operating lease right-of-use asset of \$5.9 million and \$6.2 million as of December 31, 2019 and 2018, respectively, and an aggregate lease liability of \$6.2 million and \$6.3 million, respectively, on the balance sheet. The remaining lease term is 9 years and 2 months, and the estimated incremental borrowing rate is 8.0%.

In December 2018, the Company entered into two operating leases for office space in New York and Los Angeles for approximately 4,358 and 1,293 square feet respectively. The Company recognized operating lease right-of-use assets of \$1.7 million and \$2.0 million for New York and \$0.1 million and \$0.2 million for Los Angeles as of December 31, 2019 and 2018, respectively. The Company recognized aggregate lease liabilities of \$1.7 million and \$2.0 million for New York and \$0.2 million and \$0.2 million for Los Angeles as of December 31, 2019 and 2018, respectively. The lease term for the New York operating lease is 6 years and 7 months, with no option for renewal. The lease term for the Los Angeles operating lease is 3 years with an option to extend the lease term for another 2 years which is not reasonably assured of exercise. There were no lease incentive allowances for either location. In connection with the New York lease, the Company maintained a letter of credit for the benefit of the landlord in the amount of \$0.1 million. The remaining lease terms were 5 years and 6 months for New York and 1 year and 11 months for Los Angeles at December 31, 2019 and the estimated incremental borrowing rates applied were 8.0% and 7.5%, respectively.

In February 2019, the Company entered into a lease agreement for approximately 118,000 square feet of space to develop a cell therapy manufacturing facility in Newark, California. Upon certain conditions, the Company has two ten-year options to extend the lease, both of which are not reasonably assured of exercise. The Company is entitled to a tenant improvement allowance of \$2.9 million for costs related to the design and construction of certain Company improvements. In connection with the lease, the Company will maintain a letter of credit for the benefit of the landlord in the amount of \$3.0 million. The Company started accounting for this lease in October 2019 when tenant improvement work commenced, and recognized an operating lease right-of-use asset of \$13.6 million as of December 31, 2019 and an aggregate lease liability of \$14.0 million on its balance sheet. The lease term is 188 months, and the estimated incremental borrowing rate is 9.25%.



The undiscounted future non-cancellable lease payments under our operating leases as of December 31, 2019 is as follows:

<b>Year ending December 31:</b>	<b>(in thousands)</b>
2020	\$ 5,662
2021	7,632
2022	7,951
2023	8,203
2024 and thereafter	63,864
Total undiscounted lease payments	93,312
Less: Present value adjustment	(35,920)
Less: Tenant improvement allowance	(4,367)
Total	\$ 53,025

Rent expense for the Company's operating leases was \$5.9 million and \$1.9 million for the years ended December 31, 2019 and 2018, respectively, net of lease incentives recognized. Rent expense for short-term leases was \$2.4 million and \$2.6 million for the years ended December 31, 2019 and 2018, respectively. There was a total commitment of zero and \$1.6 million at December 31, 2019 and 2018, respectively, related to short-term leases. Variable lease payments for operating expenses were \$1.1 million and immaterial for the years ended December 31, 2019 and 2018, respectively.

Certain lease agreements require the Company to return designated areas of leased space to its original condition upon termination of the lease agreement. At the inception of such leases, the Company records an asset retirement obligation and a corresponding capital asset in an amount equal to the estimated fair value of the obligation. To determine the fair value of the obligation, we estimate the cost for a third-party to perform the restoration work. In subsequent periods, for each asset retirement obligation, the Company records interest expense to accrete the asset retirement obligation liability to full value and depreciate each capitalized asset retirement obligation asset, both over the term of the associated lease agreement. Asset retirement obligations were \$0.4 million and zero as of December 31, 2019 and 2018 respectively.

#### **Note 9. Equity Method Investment**

In conjunction with the execution of the Notch Agreement (see Note 7), the Company also entered into a Share Purchase Agreement ("Notch Investment Agreement") with the Company acquiring shares of Notch's Series Seed convertible preferred stock for a total investment cost of \$5.1 million which includes transaction costs of \$0.1 million, resulting in a 25% ownership interest in Notch.

The Company's total equity investment in Notch as of December 31, 2019 was \$4.9 million and the Company accounted for the investment using the cost method of accounting. During the year ended December 31, 2019, the Company recognized its share of Notch's net loss under the other expenses caption within the statement of operations. The Company's share of Notch's net loss was \$0.2 million for the year ended December 31, 2019.

#### **Note 10. Commitments and Contingencies**

##### **Purchase Commitments**

In the normal course of business, the Company enters into various purchase commitments with third-party contract manufacturers for the manufacture and processing of our product candidates and related raw materials, and we have entered 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.

##### **Contingencies**

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnifications. The Company's exposure under these agreements is unknown, because it involves claims that may be made against the Company in the future, but have not yet been made. The Company accrues a liability for such matters when it is probable that future expenditures will be made and such expenditures can be reasonably estimated.

## **Indemnification**

In accordance with the Company's amended and restated certificate of incorporation and amended and restated bylaws, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving in such capacity. There have been no claims to date, and the Company has a directors and officers liability insurance policy that may enable it to recover a portion of any amounts paid for future claims.

### **Note 11. 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. 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 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.

On issuance, the Company elected to account for the 2018 Notes at fair value with any changes in estimated fair value being recognized through the statements of operations and comprehensive loss until the 2018 Notes settled. The fair value of the 2018 Notes was determined to be \$141.4 million upon settlement. For the years ended December 31, 2019 and 2018, the Company recognized zero and \$21.2 million, respectively, of expense in the accompanying statements of operations and comprehensive loss for 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 statements of operations and comprehensive loss.

### **Note 12. Convertible Preferred Stock and Stockholders' Equity**

#### ***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.

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.

#### ***Preferred Stock***

Pursuant to the Amended and Restated Certificate of Incorporation filed on October 15, 2018, as amended, the Company is authorized to issue a total of 10,000,000 shares of preferred stock, of which no shares were issued and outstanding at December 31, 2019 and 2018.

#### ***Common Stock***

Pursuant to the Amended and Restated Certificate of Incorporation filed on October 15, 2018, as amended, the Company is authorized to issue a total of 200,000,000 shares of common stock, of which 124,267,358 and 121,482,671 shares were issued and outstanding at December 31, 2019 and 2018, respectively.

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.

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 December 31, 2019 and 2018, no dividends on common stock had been declared by the Company's board of directors.

### Note 13. Stock-Based Compensation

#### 2018 Equity Incentive Plan

In June 2018, the Company adopted the 2018 Equity Incentive Plan (2018 Plan). The 2018 Plan provided for the Company to sell or issue common stock or restricted common stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, members of the Company's Board of Directors and consultants of the Company under terms and provisions established by the Company's Board of Directors. In October 2018, the Board of Directors approved an amendment and restatement of the 2018 Plan, increasing the shares of common stock issuable under the 2018 Plan as well as allowing for an automatic annual increase to the shares issuance under the 2018 Plan to the amount equal to 5% of the total number of shares of common stock outstanding on December 31st of the preceding calendar year. The term of any stock option granted under the 2018 Plan cannot exceed 10 years. The Company generally grants stock-based awards with service conditions only. Options granted typically vest over a four-year period but may be granted with different vesting terms. Restricted Stock Units granted typically vest annually over a four-year period but may be granted with different vesting terms. Options shall not have an exercise price less than 100% of the fair market value of the Company's common stock on the grant date. If the individual possesses more than 10% of the combined voting power of all classes of stock of the Company, the exercise price shall not be less than 110% of the fair market value of a common share of stock on the date of grant. This requirement is applicable to incentive stock options only.

As of December 31, 2019 and 2018, there were 9,642,503 and 8,176,125 shares reserved by the Company under the 2018 Plan for the future issuance of equity awards.

#### Stock Option Activity

The following summarizes option activity under the 2018 Plan:

	Outstanding Options			
	Number of Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contract Term (in years)	Aggregate Intrinsic Value (in thousands)
Balance, December 31, 2017	—	\$ —		\$ —
Options granted	12,336,975	5.47		
Options exercised	(5,020,580)	2.27		123,808
Options forfeited	(80,850)	2.27		
Balance, December 31, 2018	7,235,545	\$ 7.72	9.62	\$ 139,001
Options granted	3,052,816	27.47		
Options exercised	(711,123)	4.16		\$ 17,141
Options forfeited	(386,716)	8.79		
Balance, December 31, 2019	9,190,522	\$ 14.51	8.82	\$ 110,490
Exercisable, December 31, 2019	4,660,416	\$ 11.33	8.68	\$ 69,379
Vested and expected to vest, December 31, 2019	9,190,522	\$ 14.51	8.82	\$ 110,490

The aggregate intrinsic values of options exercised, outstanding, exercisable, vested and expected to vest were calculated as the difference between the exercise price of the options and the closing price of the Company's common stock on the Nasdaq Global Select Market on December 31, 2019. During the years ended December 31, 2019 and 2018, the estimated weighted-average grant-date fair value of employee options granted was \$18.42 per share and \$3.75 per share, respectively. As of December 31, 2019 and 2018, there was \$74.7 million and \$42.8 million, respectively, of unrecognized stock-based compensation related to unvested stock options, which is expected to be recognized over a weighted-average period of 3 years, 15 days and 3 years, 6 months, respectively.

The fair value of employee, consultant and director stock option awards was estimated at the date of grant using a Black-Scholes option-pricing model with the following assumptions:

	Year Ended December 31,	
	2019	2018
Fair value of common stock	\$25.94 - \$31.99	\$2.27 - \$26.52
Expected term in years	5.27 - 6.08	5.99 - 6.25
Expected volatility	74.14% - 74.92%	74.2% - 77.0%
Expected risk-free interest rate	1.54% - 2.62%	2.74% - 2.99%
Expected dividend	0%	0%

The Black-Scholes option-pricing model requires the use of subjective assumptions which determine the fair value of stock-based awards. These assumptions include:

*Fair value of common stock*—For grants before October 2018 when the Company was private and there was no public market for the Company’s common stock, the fair value of the Company’s common stock underlying share-based awards was estimated on each grant date by the Company’s board of directors. In order to determine the fair value of the Company’s common stock underlying option grants, the Company’s board of directors considered, among other things, valuations of the Company’s common stock prepared by an unrelated third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. For all grants subsequent to the Company’s IPO in October 2018, the fair value of common stock was determined by taking the closing price per share of common stock per Nasdaq.

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

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

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

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

For the years ended December 31, 2019 and 2018, total stock-based compensation expense related to stock options was \$21.9 million and \$3.3 million, respectively.

### **Restricted Stock Unit Activity**

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

	Outstanding Restricted Stock Units			Aggregate Intrinsic Value (in thousands)
	Restricted Stock Units	Weighted- Average Grant Date Fair Value per Share	Weighted Average Remaining Vesting Life (in years)	
Unvested December 31, 2018	—	—		—
Granted	1,982,855	\$ 27.45	1.94	
Vested	(500)	25.94		
Forfeited	(41,200)	27.48		
Unvested December 31, 2019	1,941,155	\$ 27.45	1.98	\$ 50,431
Vested and expected to vest, December 31, 2019	1,941,155	\$ 27.45	1.98	\$ 50,431

In September 2019, the Company granted 57,361 performance based restricted stock units to a certain executive officer pursuant to the 2018 Plan. These performance awards are subject to the holder's continued service to the Company through each applicable vesting event. Through December 31, 2019, the Company believes that the achievement of the requisite performance conditions for these awards are not probable and as a result, no compensation expense has been recognized related to these awards in the year ended December 31, 2019.

For the years ended December 31, 2019 and 2018, total stock-based compensation expense related to restricted stock units was \$8.8 million and zero, respectively. As of December 31, 2019 and 2018, there was \$43.0 million and zero, respectively, of unrecognized stock-based compensation which is expected to be recognized over a weighted average period of 1.98 years.

### Employee Stock Purchase Plan

In October 2018, the shareholders approved the 2018 Employee Stock Purchase Plan (ESPP), which initially reserved 1,160,000 shares of our common stock for employee purchases under terms and provisions established by the Board of Directors. Effective January 1, 2019, the number of shares authorized under the ESPP for employee purchases increased by 1,214,826 shares. The ESPP is intended to qualify as an 'employee stock purchase plan' under Section 423 of the Internal Revenue Code. Under the current offering adopted pursuant to the ESPP, each offering period is approximately 24 months, which is generally divided into four purchase periods of approximately six months.

Employees are eligible to participate if they are employed by the Company. Under the ESPP, employees may purchase common stock through payroll deductions at a price equal to 85% of the lower of the fair market value of common stock on the first trading day of each offering period or on the purchase date. The ESPP provides for consecutive, overlapping 24-month offering periods. The offering periods are scheduled to start on the first trading day on or after March 16 or September 16 of each year, except for the first offering period which commenced on October 11, 2018, the first trading day after the effective date of the Company's registration statement. Contributions under the ESPP are limited to a maximum of 15% of an employee's eligible compensation.

The fair values of the rights granted under the ESPP were calculated using the following assumptions:

	Year ended December 31,	
	2019	2018
Expected term (in years)	0.50 – 2.00	0.50 – 2.00
Volatility	60.4% - 76.0%	67.7% - 81.8%
Risk-free interest rate	1.72%-2.49%	2.37% - 2.83%
Dividend yield	—	—

For the years ended December 31, 2019 and 2018, total stock-based compensation expense related to ESPP was \$1.6 million and \$0.4 million, respectively.

### Founders' Stock

Stock-based compensation expense is recognized for shares of founders' stock as vesting conditions are met. In relation to the modification described in Note 12, 24,230,750 shares of founders' stock remained unvested at the modification date in April 2018. For the years ended December 31, 2019 and 2018, \$13.7 million and \$14.9 million of stock-based compensation expense was recognized related to the vesting of 6,057,684 and 6,562,506 shares, respectively, of founders' stock. At December 31, 2019 and 2018, there was \$30.9 million and \$44.6 million of unrecognized stock-based compensation expense related to 13,629,803 and 19,687,487 shares of unvested founders' stock which is expected to be recognized over 2 years, 3 months and 3 years, 3 months, respectively. The weighted-average fair value at grant date for founders' stock was \$2.27 per share.

Total stock-based compensation expense related to stock options, employee stock purchase plans and vesting of the founders' common stock was as follows:

	Year Ended December 31,	
	2019	2018
	(in thousands)	
Research and development	\$ 19,429	\$ 1,657
General and administrative	26,634	16,909
Total stock-based compensation expense	\$ 46,063	\$ 18,566

### **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. During the years ended December 31, 2019 and 2018, zero and 5,020,580 options were early exercised. As of December 31, 2019 and 2018, there was \$2.8 million and \$4.6 million recorded in accrued and other liabilities and \$3.9 million and \$6.8 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 financial statements since the exercise date.

### **Note 14. Related Party Transactions**

As of December 31, 2019 and 2018, Pfizer held 22,032,040 shares of Common Stock and had appointed one member to the Company's Board of Directors.

In April 2018, the Company and Pfizer entered into a transition services agreement (the Pfizer TSA) for Pfizer to provide professional services to the Company related to research and development, project management, and other administrative functions. In September 2019, the Company and Pfizer terminated the Pfizer TSA. For the years ended December 31, 2019 and 2018, the costs incurred under the Pfizer TSA were \$4.5 million and \$10.1 million, respectively.

The Company also purchased certain lab supplies and services from Pfizer in connection with its research and development activities. For the years ended December 31, 2019 and 2018, total lab supplies and services purchased from Pfizer were \$1.4 million and \$10.4 million, respectively.

As of December 31, 2019 and 2018, the Company had amounts payable to Pfizer of \$0.1 million and \$5.7 million, respectively, which were recorded in the accompanying balance sheet.

### **Consulting Agreements**

In June 2018, the Company entered into a services agreement with Two River Consulting LLC (Two River) a firm affiliated with the Company's President and Chief Executive Officer, the Company's Executive Chairman of the board of directors, and a director of the Company to provide various managerial, administrative, accounting and financial services to the Company. The costs incurred for services provided under this agreement were \$0.6 million for the years ended December 31, 2019 and 2018.

In June 2018 the Company entered into a consulting services agreement with TPG Capital – FO LLC (TPG FO) a firm affiliated with a beneficial owner of more than 5% of the Company’s capital stock. The costs incurred for services performed under this agreement were zero and \$0.3 million for the years ended December 31, 2019 and 2018, respectively.

In August 2018, the Company entered into a consulting agreement with Bellco Capital LLC (Bellco). The Company’s executive chairman, Arie Beldegrun, 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. Beldegrun and include without limitation, providing advice and analysis with respect to the Company’s business, business strategy and potential opportunities in the field of allogeneic CAR T cell therapy and any other aspect of the CAR T cell therapy business as the Company may agree. In consideration for these services, the Company paid Bellco \$26,250 per month in arrears commencing June 2018. Beginning January 2019, the Company paid Bellco \$33,333.33 per month in arrears and, at 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 costs incurred for services provided, bonus and out-of-pocket expenses incurred under this consulting agreement were \$0.8 million and \$0.5 million for the years ended December 31, 2019 and 2018, respectively.

**Sublease Agreements**

In December 2018, the Company entered into a sublease with Bellco for 1,293 square feet of office space in Los Angeles California for a three year term. The total right of use asset and associated liability recorded related to this related party lease was \$0.1 million and \$0.2 million at December 31, 2019 and 2018, respectively.

In February 2019, the Company subleased 2,180 square feet of its office space in New York, New York, to ByHeart, Inc., formerly known as Second Science, Inc. (ByHeart). ByHeart is a development-stage infant formula company. Two of the Company’s board members have beneficial ownership in ByHeart and one serves on the board of directors of ByHeart. In September 2019, the Company entered into an amendment to the sublease agreement and increased the subleased space to 2,907 square feet. Sublease income for the year ended December 31, 2019 was \$0.3 million and was recognized as other income.

**Note 15. 401(k) Plan**

In April 2018, the Company began to sponsor a 401(k) retirement savings plan for the benefit of its employees. All employees are eligible to participate, provided they meet the requirements of the plan. The Company made contributions to the plan for eligible participants, and recorded contribution expenses of \$0.9 million and \$0.4 million related to matched contributions for the year ended December 31, 2019 and 2018, respectively.

**Note 16. Income Taxes**

For the years ended December 31, 2019 and 2018, the Company recorded income tax benefit due to the intraperiod tax allocation of deferred income taxes on unrealized gains on available for sale securities recorded in other comprehensive income. The Company has incurred net operating losses for all the periods presented. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying financial statements.

The Company has established a full valuation allowance against its deferred tax assets due to the uncertainty surrounding the realization of such assets.

	Year Ended December 31,		Period from
	2019	2018	November 30, 2017 (Inception) to December 31, 2017
	(in thousands)		
Current:			
Federal	\$ —	\$ —	\$ —
State	1	2	—
	1	2	—
Deferred:			
Federal	(251)	(89)	—
State	(81)	(30)	—
	(332)	(119)	—
Benefit for income taxes	\$ (331)	\$ (117)	\$ —

Reconciliation of the benefit for income taxes calculated at the statutory rate to our benefit for income taxes is as follows:

	Year Ended December 31,		Period from
	2019	2018	November 30, 2017 (Inception) to December 31, 2017
	(in thousands)		
Tax benefit at federal statutory rate	\$ (38,834)	\$ (44,441)	\$ —
State taxes, net of federal benefit	(12,951)	(10,652)	—
Stock-based compensation	2,037	3,629	—
Research tax credits	(1,714)	(708)	—
Write-off of in-process R&D	—	5,247	—
Change in fair value of convertible notes	—	4,454	—
Change in valuation allowance	49,989	41,916	—
Other	1,141	438	—
Benefit for incomes taxes	\$ (331)	\$ (117)	\$ —

Deferred income taxes reflect the net tax effects of (a) temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes, and (b) operating losses and tax credit carryforwards.

Significant components of our deferred tax assets and liabilities are as follows:



	Year Ended December 31,		Period from November 30, 2017 (Inception) to December 31
	2019	2018	2017
	(in thousands)		
Deferred tax assets:			
Net operating loss carryforwards	\$ 54,018	\$ 16,437	\$ —
Tax credit carryforwards	4,239	1,239	—
Intangibles	22,770	23,086	—
Accrued expenses	2,375	952	—
Lease liabilities	14,839	9,730	—
Stock based compensation	6,870	360	—
Other	—	—	—
Total deferred tax assets	105,111	51,804	—
Deferred tax liabilities:			
Fixed assets	(361)	(531)	—
Right of use leased assets	(12,453)	(9,239)	—
Investments	(393)	(118)	—
Other	—	—	—
Total deferred tax liabilities	(13,207)	(9,888)	—
Net deferred tax assets	91,904	41,916	—
Valuation allowance	(91,904)	(41,916)	—
Net deferred tax assets	\$ —	\$ —	\$ —

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Due to the lack of earnings history, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance increased by approximately \$50.0 million and \$41.9 million during the years ended December 31, 2019 and December 31, 2018, respectively.

The following table sets forth our federal and state NOL carryforwards and federal research and development tax credits as of December 31, 2019:

	Amount	Expiration
	(in thousands)	
Net operating losses, federal	\$ 193,991	Indefinite
Net operating losses, federal	\$ 2	2037
Net operating losses, state	\$ 190,159	2037-2039
Tax credits, federal	\$ 4,037	2038-2039
Tax credits, state	\$ 3,832	Indefinite

Current federal and California tax laws include substantial restrictions on the utilization of NOLs and tax credit carryforwards in the event of an ownership change of a corporation. Accordingly, the Company's ability to utilize NOLs and tax credit carryforwards may be limited as a result of such ownership changes. Such a limitation could result in the expiration of carryforwards before they are utilized.

Income tax expense or benefit from continuing operations is generally determined without regard to other categories of earnings, such as discontinued operations and other comprehensive income. An exception is provided in ASC 740 when there is aggregate income from categories other than continuing operations and a loss from continuing operations in the current year. In this case, the tax benefit allocated to continuing operations is the amount by which the loss from continuing operations reduces the tax expenses recorded with respect to the other categories of earnings, even when a valuation allowance has been established against the deferred tax assets. In instances where a valuation allowance is established against current year losses, income from other sources, including gain from available-for-sale investments recorded as a component of other comprehensive

income, is considered when determining whether sufficient future taxable income exists to realize the deferred tax assets. For the years ended December 31, 2019 and 2018, the Company recorded a tax benefit of \$0.3 million and \$0.1 million, respectively, in other comprehensive income, related to available-for-sale securities.

We apply the provisions of ASC Topic 740 to account for uncertain income tax positions. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows:

	December 31,		
	2019	2018	2017
	(in thousands)		
Balance at beginning of the year:	920	—	—
Additions based on tax positions related to current year	2,228	920	—
Additions to tax position of prior year	—	—	—
Reductions to tax position of prior years	—	—	—
Lapse of the applicable statute of limitations	—	—	—
Balance at end of the year	\$ 3,148	\$ 920	\$ —

It is the Company's policy to include penalties and interest expense related to income taxes as a component of interest and other income, net, as necessary. As of December 31, 2019 and 2018, there were no accrued interest and penalties related to uncertain tax positions. The reversal of the uncertain tax benefits would not affect the effective tax rate to the extent that the Company continues to maintain a full valuation allowance against its deferred tax assets. Unrecognized tax benefits may change during the next 12 months for items that arise in the ordinary course of business. We are subject to examination by U.S. federal or state tax authorities for all years since inception.

#### Note 17. Net Loss and Net Loss Per Share

The following table sets forth the computation of the basic and diluted net loss per share (in thousands, except share and per share data):

	Year Ended December 31,		Period From November 30, 2017 (Inception) to December 31,
	2019	2018	2017
Numerator:			
Net loss	\$ (184,594)	\$ (211,505)	\$ (2)
Denominator:			
Weighted average common shares outstanding	101,061,149	28,948,386	26,249,993
Net loss per share, basic and diluted	\$ (1.83)	\$ (7.31)	\$ —

Since the Company was in a loss position for all periods presented, basic net loss per share is the same as diluted net loss per share as the inclusion of all potential dilutive securities would have been anti-dilutive. Potentially dilutive securities that were not included in the diluted per share calculations because they would be anti-dilutive were as follows:

	Year Ended December 31,		Period From November 30, 2017 (Inception) to December 31,
	2019	2018	2017
Stock options to purchase common stock	9,190,522	7,235,545	—
Restricted stock units subject to vesting	1,941,155	—	—
Expected shares purchased under Employee Stock Purchase Plan	195,161	144,272	—
Founder shares subject to future vesting	13,629,803	19,687,487	—
Early exercised stock options subject to future vesting	2,992,290	5,020,580	—
Total	27,948,931	32,087,884	—

**Note 18. Subsequent Events**

From January 6 to January 17, 2020, the Company sold an aggregate of 570,839 shares of common stock in ATM offerings resulting in net proceeds of \$14.8 million.

**Note 19. Selected Quarterly Financial Data (unaudited)**

The following table provides the selected quarterly financial data for the year ended December 31, 2019 (in thousands, except per share amounts):

	Quarter Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Loss from operations	\$ (36,461)	\$ (45,961)	\$ (55,011)	\$ (64,575)
Net loss	(31,586)	(41,243)	(50,735)	(61,030)
Net loss per share, basic and diluted	\$ (0.32)	\$ (0.41)	\$ (0.50)	\$ (0.58)

The following table provides the selected quarterly financial data for the year ended December 31, 2018 (in thousands, except per share amounts):

	Quarter Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Loss from operations	\$ 2,597	\$ 135,012	\$ 22,187	\$ 33,046
Net loss	(2,597)	(134,902)	(43,497)	(30,509)
Net loss per share, basic and diluted	\$ (0.10)	\$ (43.82)	\$ (10.71)	\$ (0.37)

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

**Item 9A. Controls and Procedures.****Conclusions Regarding the Effectiveness of Disclosure Controls and Procedures**

As of December 31, 2019, management, with the participation of our Chief Executive Officer and Chief Financial Officer, performed an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures.

Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2019, the design and operation of our disclosure controls and procedures were effective at a reasonable assurance level.

**Management's Annual Report on Internal Controls Over Financial Reporting**

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has assessed the effectiveness of our internal control over financial reporting based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework (2013 framework). Based on our evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2019.

The effectiveness of our internal control over financial reporting has been audited by Ernst & Young LLP, an independent registered public accounting firm, as stated in their attestation report herein, which expresses an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2019.

### **Inherent Limitations of Internal Controls**

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risks that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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

We regularly review our system of internal control over financial reporting and make changes to our processes and systems to improve controls and increase efficiency, while ensuring that we maintain an effective internal control environment. Changes may include such activities as implementing new, more efficient systems, consolidating activities, and migrating processes. There were no changes in our internal control over financial reporting that occurred during the most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **Report of Independent Registered Public Accounting Firm**

To the Stockholders and the Board of Directors of Allogene Therapeutic, Inc.

### **Opinion on Internal Control Over Financial Reporting**

We have audited Allogene Therapeutic, Inc.'s internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Allogene Therapeutic, Inc. (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the 2019 financial statements of the Company and our report dated February 27, 2020 expressed an unqualified opinion thereon.

### **Basis for Opinion**

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

### **Definition and Limitations of Internal Control Over Financial Reporting**

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

San Jose, California  
February 27, 2020

**Item 9B. Other Information.**

None.

## PART III

### **Item 10. Directors, Executive Officers and Corporate Governance.**

The information required by this Item and not set forth below will be set forth in the section headed “—Election of Directors” and “Information Regarding the Board of Directors and Corporate Governance” in our definitive Proxy Statement for our 2020 Annual Meeting of Stockholders to be filed with the SEC by April 29, 2020 (our Proxy Statement) and is incorporated in this Annual Report by reference.

We have adopted a code of ethics for directors, officers (including our principal executive officer, principal financial officer and principal accounting officer) and employees, known as the Code of Business Conduct and Ethics. The Code of Business Conduct and Ethics is available on our website at <http://www.allogene.com> under the Governance section of our Investors page. We will promptly disclose on our website (i) the nature of any amendment to the policy that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (ii) the nature of any waiver, including an implicit waiver, from a provision of the policy that is granted to one of these specified individuals, the name of such person who is granted the waiver and the date of the waiver. Shareholders may request a free copy of the Code of Business Conduct and Ethics from our Compliance Officer, c/o Allogene Therapeutics, Inc., 210 E. Grand Ave, South San Francisco, CA 94080.

### **Item 11. Executive Compensation.**

The information required by this Item will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated in this Annual Report by reference.

### **Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

The information required by this Item will be set forth in the section headed “Security Ownership of Certain Beneficial Owners and Management” in our Proxy Statement and is incorporated in this Annual Report by reference.

Information regarding our equity compensation plans will be set forth in the section headed “Executive Compensation” in our Proxy Statement and is incorporated in this Annual Report by reference.

### **Item 13. Certain Relationships and Related Transactions, and Director Independence.**

The information required by this Item will be set forth in the section headed “Transactions With Related Persons” in our Proxy Statement and is incorporated in this Annual Report by reference.

### **Item 14. Principal Accounting Fees and Services.**

The information required by this Item will be set forth in the section headed “—Ratification of Selection of Independent Registered Public Accounting Firm” in our Proxy Statement and is incorporated in this Annual Report by reference.

**PART IV****Item 15. Exhibits, Financial Statement Schedules.**

## (a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Part II, Item 8 above.

## (a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Financial Statements or Notes thereto set forth under Item 8 above.

## (a)(3) Exhibits.

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report.

Exhibit Number	Exhibit Index Description
3.1	<a href="#">Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38693), filed with the SEC on October 15, 2018).</a>
3.2	<a href="#">Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-38693), filed with the SEC on October 15, 2018).</a>
4.1	Reference is made to Exhibits <a href="#">3.1</a> and <a href="#">3.2</a>
4.2	<a href="#">Form of Common Stock Certificate of the Registrant (incorporated by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on October 2, 2018).</a>
4.3	<a href="#">Description of Common Stock.</a>
4.4	<a href="#">Investors' Rights Agreement, dated April 6, 2018, by and among the Registrant and certain of its securityholders, as amended September 5, 2018, (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on September 14, 2018)</a>
10.1+	<a href="#">Form of Indemnity Agreement by and between the Registrant and its directors and officers (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on October 2, 2018).</a>
10.2+	<a href="#">Indemnification Agreement, dated April 6, 2018, by and between the Registrant and John DeYoung (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on October 2, 2018).</a>
10.3+	<a href="#">Allogene Therapeutics, Inc. Amended and Restated 2018 Equity Incentive Plan (Prior Plan) and Forms of Stock Option Grant Notice, Option Agreement, Notice of Exercise and Early Exercise Stock Purchase Agreement thereunder, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on September 14, 2018).</a>
10.4+	<a href="#">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).</a>
10.5+	<a href="#">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).</a>
10.6+	<a href="#">Allogene Therapeutics, Inc. 2018 Change in Control Plan 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).</a>
10.7+	<a href="#">Non-Employee Director Compensation Policy.</a>
10.8+	<a href="#">Employment Agreement by and between the Registrant and David Chang, M.D., Ph.D. (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on September 14, 2018).</a>

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10.9+	<a href="#">Employment Agreement by and between the Registrant and Eric Schmidt, Ph.D. (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on September 14, 2018).</a>
10.10+	<a href="#">Employment Agreement by and between the Registrant and Alison Moore, Ph.D. (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on September 14, 2018).</a>
10.11+	<a href="#">Employment Letter of Agreement, dated July 29, 2019, by and between the Registrant and Rafael G. Amado, M.D.</a>
10.12*	<a href="#">License Agreement, dated March 8, 2019, between the Registrant and Collectis S.A. (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on May 7, 2019).</a>
10.13†	<a href="#">Exclusive License and Collaboration Agreement, dated October 30, 2015, by and between the Registrant (assignee of Pfizer Inc.) and Les Laboratoires Servier and Institut de Recherches Internationales Servier (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 September 17, 2018).</a>
10.14†	<a href="#">Asset Contribution Agreement, dated April 2, 2018, by and between the Registrant and Pfizer Inc. (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1, as amended (File No. 333-227333), filed with the SEC on September 14, 2018).</a>
10.15*	<a href="#">Collaboration and License Agreement, dated November 1, 2019, by and between the Registrant and Notch Therapeutics Inc.</a>
10.16	<a href="#">Lease, dated August 1, 2018, by and between the Registrant and Britannia Pointe Grand Limited Partnership. (incorporated by reference to Exhibit 10.11 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).</a>
10.17	<a href="#">Lease Agreement, dated October 25, 2018, by and between the Registrant and HCP, Inc. (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on March 8, 2019).</a>
10.18	<a href="#">Lease Agreement, dated February 19, 2019, by and between the Registrant and Silicon Valley Gateway Technology Center, LLC (incorporated by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-38693), filed with the SEC on March 8, 2019).</a>
10.19	<a href="#">First Amendment, dated September 4, 2019, to the Lease Agreement, dated February 19, 2019, by and between the Registrant and Silicon Valley Gateway Technology Center, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-38693), filed with the SEC on November 5, 2019).</a>
10.20	<a href="#">Sales Agreement, dated November 5, 2019, by and between the Registrant and Cowen and Company, LLC (incorporated by reference to Exhibit 1.2 to the Registrant's Registration Statement on Form S-3 (File No. 333-234516), filed with the SEC on November 5, 2019).</a>
23.1	<a href="#">Consent of Independent Registered Public Accounting Firm.</a>
24.1	<a href="#">Power of Attorney. Reference is made to the signature page hereto.</a>
31.1	<a href="#">Certification of Principal Executive Officer 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.</a>
31.2	<a href="#">Certification of Principal Financial Officer 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.</a>
32.1	<a href="#">Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2	<a href="#">Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS	XBRL Instance Document
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.



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- † Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission
- \* Certain portions of this exhibit (indicated by “[\*\*\*]”) have been omitted as the Registrant has determined (i) the omitted information is not material and (ii) the omitted information would likely cause harm to the Registrant if publicly disclosed.

**Item 16. Form 10-K Summary**

None.

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized, in South San Francisco, California, on February 27, 2020.

**Allogene Therapeutics, Inc.**

By:           /s/ David Chang, M.D., Ph.D.  
 David Chang, M.D., Ph.D.  
 President, Chief Executive Officer and Member of the Board of Directors  
 (Principal Executive Officer)

**POWER OF ATTORNEY**

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints David Chang, M.D., Ph.D. and Eric Schmidt, Ph.D., and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
<u>          /s/ David Chang, M.D., Ph.D.</u> David Chang, M.D., Ph.D.	President, Chief Executive Officer and Member of the Board of Directors <i>(Principal Executive Officer)</i>	February 27, 2020
<u>          /s/ Eric Schmidt, Ph.D.</u> Eric Schmidt, Ph.D.	Chief Financial Officer <i>(Principal Financial and Accounting Officer)</i>	February 27, 2020
<u>          /s/ Arie Belldegrun, M.D., FACS</u> Arie Belldegrun, M.D., FACS	Executive Chairman of the Board of Directors	February 27, 2020
<u>          /s/ David Bonderman</u> David Bonderman	Member of the Board of Directors	February 27, 2020
<u>          /s/ John DeYoung</u> John DeYoung	Member of the Board of Directors	February 27, 2020
<u>          /s/ Franz Humer, Ph.D.</u> Franz Humer, Ph.D.	Member of the Board of Directors	February 27, 2020
<u>          /s/ Joshua Kazam</u> Joshua Kazam	Member of the Board of Directors	February 27, 2020
<u>          /s/ Deborah M. Messemer</u> Deborah M. Messemer	Member of the Board of Directors	February 27, 2020
<u>          /s/ Todd Sisitsky</u> Todd Sisitsky	Member of the Board of Directors	February 27, 2020
<u>          /s/ Owen Witte, M.D.</u> Owen Witte, M.D.	Member of the Board of Directors	February 27, 2020

## DESCRIPTION OF COMMON STOCK

### General

The following description summarizes the most important terms of our common stock. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of the matters set forth in this “Description of Common Stock,” you should refer to our amended and restated certificate of incorporation (the “Restated Certificate”) and amended and restated bylaws (the “Restated Bylaws”), which are included as exhibits to our Annual Report on Form 10-K, and to the applicable provisions of Delaware law. Our authorized capital stock consists of 200,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share. Our board of directors has the authority, without stockholder approval, except as required by the listing standards of The Nasdaq Stock Market LLC, to issue additional shares of our capital stock. In addition, our board of directors has the authority, without further action by our stockholders, to designate the rights, preferences, privileges, qualifications and restrictions of our preferred stock in one or more series.

### Voting Rights

Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

### Dividends and Distributions

Subject to preferences that may be applicable to any then-outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

### Liquidation, Dissolution or Winding Up

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

### Other Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

### Fully Paid and Nonassessable

All of our outstanding shares of common stock are fully paid and nonassessable.

### Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC.

### Stock Exchange Listing

Our common stock is listed on The Nasdaq Global Select Market under the symbol “ALLO.”

### Anti-Takeover Provisions

#### *Delaware Anti-Takeover Law*

We are subject to Section 203 of the Delaware General Corporation Law (“DGCL”), which generally prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding upon consummation of the transaction, excluding for purposes of determining the number of shares outstanding (1) shares owned by persons who are directors and also officers and (2) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the consummation of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned

by the interested stockholder.

Section 203 of the DGCL defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 of the DGCL defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

#### ***Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws Provisions***

Provisions of the Restated Certificate and the Restated Bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, the Restated Certificate and the Restated Bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66 2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66 2/3% of our then outstanding common stock.

The foregoing provisions may make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage certain types of transactions that may involve an actual or threatened acquisition of us. These provisions are also designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions also may inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

#### **Choice of Forum**

Our Restated Certificate and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the

State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) shall be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors or officers or other employees arising out of or pursuant to any provision of the DGCL, our Restated Certificate or Restated Bylaws (including any right, obligation, or remedy thereunder); (iv) any action or proceeding as to which the DGCL confers jurisdiction to the Court of Chancery of the State of Delaware; and (v) any action asserting a claim against us or any of our directors or officers or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. This choice of forum provision does not apply to suits brought to enforce a duty or liability created by the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts have exclusive jurisdiction.

Further, our Restated Certificate and Restated Bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended.

**ALLOGENE THERAPEUTICS, INC.**  
**NON-EMPLOYEE DIRECTOR COMPENSATION POLICY ADOPTED: SEPTEMBER 26,**  
**2018**  
**AMENDED: APRIL 16, 2019**

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

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

### **Annual Cash Compensation**

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

1. Annual Board Service Retainer:
  - a. All Eligible Directors: \$40,000
2. Annual Committee Member Service Retainer:
  - a. Member of the Audit Committee: \$12,500
  - b. Member of the Compensation Committee: \$7,500
  - c. Member of the Nominating and Corporate Governance Committee: \$5,000
3. Annual Committee Chair Service Retainer (in lieu of Committee Member Service Retainer):
  - a. Chairman of the Audit Committee: \$25,000
  - b. Chairman of the Compensation Committee: \$15,000
  - c. Chairman of the Nominating and Corporate Governance Committee: \$10,000

### **Equity Compensation**

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

**(a) Automatic Equity Grants.**

(i) **Initial Grant for New Directors.** Without any further action of the Board, each person who, after the IPO, is elected or appointed for the first time to be a Non-Employee Director will automatically, upon the date of his or her initial election or appointment to be a Non-Employee Director (or, if such date is not a market trading day, the first market trading day thereafter), be granted (i) a Nonstatutory Stock Option to purchase shares of common stock of the Company (the “**Initial Option Grant**”) and (ii) a restricted stock unit award covering shares of common stock of the Company (the “**Initial RSU Grant**”), whereby the Initial Option Grant and Initial RSU Grant shall together have a total grant date value of \$850,000 (with the shares covered by the award rounded down to the nearest whole share). The recipient shall designate the proportionate share between the Initial Option Grant and Initial RSU Grant prior to or on the date of grant. The grant date value will be calculated in accordance with the Black-Scholes option valuation methodology or such other methodology as the Board or the Compensation Committee of the Board may determine prior to the grant of such award. Each Initial Option Grant will vest in a series of 36 successive equal monthly installments over the three-year period measured from the date of grant. Each Initial RSU Grant will vest in a series of three successive equal annual installments over the three-year period measured from the date of grant.

(ii) **Annual Grant.** Without any further action of the Board, at the close of business on the date of each Annual Meeting following the IPO, each person who is then a Non-Employee Director will automatically be granted (i) a Nonstatutory Stock Option to purchase shares of common stock (the “**Annual Option Grant**”) and (ii) a restricted stock unit award covering shares of common stock of the Company (the “**Annual RSU Grant**”), whereby the Annual Option Grant and Annual RSU Grant shall together have a total grant date value of \$425,000 (with the shares covered by the award rounded down to the nearest whole share). The recipient shall designate the proportionate share between the Annual Option Grant and Annual RSU Grant prior to or on the date of grant. The grant date value will be calculated in accordance with the Black-Scholes option valuation methodology or such other methodology as the Board or the Compensation Committee of the Board may determine prior to the grant of such award. Each Annual Option Grant will vest in a series of 12 successive equal monthly installments over the one-year period measured from the date of grant. Each Annual RSU Grant will vest on the one-year anniversary of the date of grant.

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

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

## Expenses

The Company will reimburse Non-Employee Director for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; *provided*, that the Non-Employee Director timely submit to the Company appropriate

documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.



July 29, 2019

Rafael G. Amado, M.D.

**Re: Employment Letter of Agreement (“Agreement”)**

Dear Dr. Amado,

Allogene Therapeutics, Inc. (“Allogene” or the “Company”) is pleased to offer you employment on the following terms and conditions.

1. Title; Reporting; Duties.

- (a) When you commence employment with Allogene, you shall be employed in the position of Executive Vice President of Research and Development and Chief Medical Officer, shall report directly to David Chang, Chief Executive Officer and President, and shall perform the duties and responsibilities that the Company assigns to you.
- (b) You shall devote substantially all of your business time, attention and energies to the business and affairs of Allogene and shall not during the period of your employment be actively engaged in any other business activity, whether or not such business activity is pursued for gain, profit or other pecuniary advantage, that will materially interfere with the performance of your duties or your availability to perform such duties or that will adversely affect, or negatively reflect upon, Allogene.
- (c) Your duties will be performed from 210 E. Grand Ave, South San Francisco, CA 94080. Reasonable out of pocket travel expenses incurred for visiting Allogene’s offices prior to relocation to the San Francisco Bay Area as described in Section 5 will be reimbursed by Allogene.

2. Compensation.

- (a) Base Salary. You shall receive base salary paid at the rate of five hundred thousand dollars (\$500,000) per year, payable in accordance with Allogene’s payroll practices.
- (b) Bonus. You will be eligible to earn an annual performance bonus at the sole discretion of the Company in an amount equal to a target of forty percent (40%) of your base salary (the “Annual Bonus”). The Annual Bonus will be based upon the Company’s assessment of your performance and the Company’s attainment of targeted goals as set by the Company in its sole discretion. Following the close of each calendar year, the Company will determine whether you have earned an Annual Bonus, and the amount of any such bonus, based on the achievement of such goals. No amount of Annual Bonus is guaranteed, and you must be an employee on the Annual Bonus payment date to be eligible to receive an Annual Bonus. No partial or prorated bonuses will be provided (except that for calendar year 2019, any bonus will be based upon the time of your employment with the Company in 2019). The Annual Bonus, if earned, will be paid no later than March 15 of the calendar year after the applicable bonus year.
- (c) Withholding. Allogene shall withhold all applicable federal, state and local taxes and social security and such other amounts as may be required by law from all amounts payable under this Section 2.

3. Options and RSUs.

- (a) Options. Subject to the approval of the Board of Directors (the “Board”), or an authorized committee thereof, you shall be granted a stock option having an aggregate grant date value of \$2.75 million for the purchase of shares of Allogene’s common stock, par value \$0.001 per share (the “Common Stock”) on your employment start date. The grant date value will be calculated in accordance with the Black-Scholes option valuation methodology or such other methodology as the Board or the Compensation Committee of the Board may determine prior to the grant of such award (with the shares covered by the award rounded down to the nearest whole share). Such grant shall be evidenced by an option agreement

(the "Option Agreement") to be entered into by and between you and the Company. In the event of a conflict between this Agreement and the Option Agreement, the terms of the Option Agreement shall control. The exercise price per option share will be equal to the fair market value per share of the Company's common stock as of the date that such Option is granted by the Board. The Option shall have a 10-year term and shall vest and become exercisable as follows: (i) 25% upon the first anniversary date of your employment start date (the "Initial Vesting Date"); and thereafter (ii) the remaining unvested options shares shall vest in 36 equal monthly installments following the Initial Vesting Date and measured from the first anniversary of the Initial Vesting Date.

- (b) **Restricted Stock Units:** Subject to the approval of the Board, or an authorized committee thereof, you shall be granted a restricted stock unit ("RSU") in the amount of a number of shares equal to \$2.75 million divided by the closing price per share of the Company's Common Stock on The NASDAQ Global Select Market on your employment start date (with the shares covered by the award rounded down to the nearest whole share). Such grant shall be evidenced by a Restricted Stock Unit Agreement (the "Award Agreement") to be entered into by and between you and the Company. In the event of a conflict between this Agreement and the Award Agreement, the terms of the Award Agreement shall control. The RSU shall vest in four (4) equal annual installments as of the annual anniversary of the last calendar day of the month of your employment start date.
  - (c) **Performance RSU.** Subject to the approval of the Board, or an authorized committee thereof, you shall be granted an additional restricted stock unit ("Performance RSU") in the amount of a number of shares equal to \$1.5 million divided by the closing price per share of the Company's Common Stock on The NASDAQ Global Select Market on your employment start date (with the shares covered by the award rounded down to the nearest whole share). Such grant shall be evidenced by a Restricted Stock Unit Agreement (the "Performance Award Agreement") to be entered into by and between you and the Company. In the event of a conflict between this Agreement and the Performance Award Agreement, the terms of the Performance Award Agreement shall control. The Performance RSU shall vest in three (3) equal annual installments, with (a) the first installment to vest upon initiation of a Phase 2 clinical trial of ALLO-501, (b) the second installment to vest upon the filing of a biologics license application with the U.S. Food and Drug Administration ("FDA") for ALLO-501, and (c) the third installment to vest upon FDA approval of ALLO-501. Any unvested portion of the Performance RSU shall lapse after seven (7) years.
4. **Sign-On Advance.** You will receive a sign-on advance in the amount of seventy-five thousand dollars (\$75,000), subject to standard payroll deductions and withholdings, payable within thirty (30) days after your employment start date (the "Sign-On Advance"). The Sign-On Advance will be considered earned only if you successfully complete one (1) year of continuous employment with the Company. If within your first year of employment with the Company: (a) you resign your employment, or (b) the Company terminates your employment for Cause (as defined below), then you agree to pay back the entire amount of the Sign-on Advance within ten (10) days after your employment termination date. For purposes of this Agreement, "Cause" will mean any one or more of the following: (a) commission of any felony or crime involving dishonesty; (b) participation in any fraud against the Company; (c) material breach of your contractual, statutory or common law duties to the Company (including violation of any provision or obligation under this Agreement); (d) your failure to satisfactorily perform your job duties as assigned by the Company; (e) intentional damage to any property of the Company; or (f) misconduct or other violation of Company policy that causes or reasonably could cause harm.
5. **Relocation Advance.** We understand you will be relocating to the San Francisco Bay Area. In connection with that relocation you will receive a relocation advance payment in the amount of one-hundred fifty thousand dollars (\$150,000), subject to standard payroll deductions and withholdings, payable within thirty (30) days of your start date (the "Relocation Advance"). The Relocation Advance will be considered earned only if you relocate to the San Francisco Bay Area on or before December 31, 2019 and you successfully complete one (1) year of continuous employment with the Company. You may use the Relocation Advance to pay for relocation expenses or for any other purpose. If within your first year of employment with the Company: (a) you resign your employment, or (b) the Company terminates your employment for Cause (as defined above), then you agree to pay back the entire amount of the Relocation Advance within ten (10) days after your employment termination date.
6. **Expenses.** Allogene will reimburse you for all normal, usual and necessary expenses incurred in furtherance of the business and affairs of Allogene upon timely receipt by Allogene of appropriate vouchers or other proof of

your expenditures and otherwise in accordance with any expense reimbursement and approval policy as may from time to time be adopted by Allogene.

7. Benefits. As a regular full-time employee, you shall be entitled to participate in the employee benefits made available to similarly situated employees, in accordance with the terms of such benefits plans and programs and company policies. Information regarding these employee benefits is available upon request and in the official plan documents, summary plan descriptions, and applicable summaries. The Company, in its sole discretion, has the right to amend or terminate any benefit plan, program or Company policy at any time and without prior notice.
8. Representations and Warranties. You hereby represent and warrant as follows:
  - (a) By accepting the Company's offer of employment, you represent that you have no agreements, relationships, or commitments with any other person or entity that conflict with your obligations to the Company.
  - (b) You have the full right, power and legal capacity to enter and deliver this Agreement and to perform your duties and other obligations hereunder. This Agreement constitutes the legal, valid and binding obligation of the parties, enforceable against each in accordance with its terms. No approvals or consents of any persons or entities are required for you to execute and deliver this Agreement or perform your duties and other obligations hereunder.
  - (c) You represent and warrant to the Company that you have not brought and shall not bring with you to the Company, or use in the performance of your duties, any materials or documents of any former employer that are not generally available to the public, unless you have obtained written authorization from the former employer for their possession and use and provided the Company with a copy thereof.
9. Conditions to Employment. This offer of employment is contingent upon, and your employment shall be subject to:
  - (a) completion of reference checks and background check, and may be contingent upon a drug screen, each to the reasonable satisfaction of Allogene; and
  - (b) satisfying the requirements of the Immigration Control and Reform Act, which may be accomplished by showing your proof of right to work in the U.S. within three days of commencing employment, and you agree to assist as needed at the Company's request to meet these conditions.
  - (c) execution of Allogene's form of Employee Confidential Information and Invention Assignment Agreement attached hereto as Exhibit A, which prohibits unauthorized use or disclosure of Allogene's proprietary information, among other obligations;
  - (d) Notwithstanding the foregoing, this offer may be withdrawn by Allogene at any time prior to its execution by the parties.
10. Employment-at-will and Termination. Your employment shall be at-will. Accordingly, you may terminate your employment with Allogene at any time and for any reason whatsoever, with or without advance notice, simply by notifying Allogene in writing. Similarly, Allogene may terminate your employment at any time and for any reason whatsoever, with or without cause or advance notice. This at-will relationship cannot be changed except in a writing signed by the Company's General Counsel and you. The employment terms contained in this Agreement supersede any other agreements and promises made to you by Allogene or any representative on its behalf, whether oral, written or implied.
11. No Reliance by You on Promise or Representation Not in this Agreement. In accepting employment with Allogene and signing this Agreement, you agree that you are not relying on any representation, promise or inducement that has been made by Allogene or any representative on its behalf that is not explicitly stated in this Agreement. Allogene is not bound by and will not be liable for any representation, promise or inducement that is not explicitly stated in this Agreement.
12. Governing Law. The terms of this offer letter shall be governed by, and construed and interpreted in accordance with, the laws of the State of California without regard to such State's principles of conflict of laws, except as provided in Section 13.

13. Arbitration. To the maximum extent permitted by law, any dispute between the parties, including but not limited to those arising out of, or relating to, this Agreement, shall be exclusively decided by binding arbitration in accordance with the terms of the Arbitration Agreement, which is attached as Exhibit B and incorporated into this Agreement. The Federal Arbitration Act shall govern the interpretation, enforcement and all proceedings pursuant to the Arbitration Agreement. To the extent that the Federal Arbitration Act is inapplicable, the terms of the Arbitration Agreement shall be construed in accordance with California law.
14. Miscellaneous.
- (a) This Agreement, and your rights and obligations hereunder, may not be assigned. Allogene may assign its rights, together with its obligations, hereunder in connection with any sale, transfer or other disposition of all or substantially all of its business or assets, provided the assignee entity which succeeds to Allogene expressly assumes Allogene's obligations hereunder and complies with the terms of this Agreement.
  - (b) This Agreement cannot be amended orally, or by any course of conduct or dealing, but only by a written agreement signed by the parties hereto. The Company's signatory must be an officer who is authorized by the Company to enter into such an amendment.
  - (c) The failure of either party to insist upon the strict performance of any of the terms, conditions and provisions of this Agreement shall not be construed as a waiver or relinquishment of future compliance therewith, and such terms, conditions and provisions shall remain in full force and effect. No waiver of any term or condition of this Agreement on the part of either party shall be effective for any purpose whatsoever unless such waiver is in writing and signed by such party. If any provision of this offer letter agreement is determined to be invalid or unenforceable, in whole or in part, this determination shall not affect any other provision of this offer letter agreement and the provision in question shall be modified so as to be rendered enforceable in a manner consistent with the intent of the parties insofar as possible under applicable law.
  - (d) This Agreement, including its Exhibits A and B, sets forth the entire agreement and understanding of the parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, relating to the subject matter of the Agreement. This letter may be delivered and executed via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and shall be deemed to have been duly and validly delivered and executed and be valid and effective for all purposes.
15. Certification of Qualifications. By accepting employment, you certify that the information you provided to Allogene about your experience, education and other qualifications for employment has been accurate and complete.

If you wish to accept employment at Allogene under the terms described above, please sign and date this Agreement, and return it to me. If you accept this offer, we would like you to start employment on Tuesday, September 3, 2019.

We look forward to your favorable reply and to a productive and enjoyable working relationship.

This offer will be deemed withdrawn if not accepted by August 2, 2019.

Sincerely,

/s/ Veer Bhavnagri

\_\_\_\_\_  
Veer Bhavnagri  
Allogene Therapeutics, Inc.

Understood and Accepted:

/s/ Rafael G. Amado

\_\_\_\_\_  
Rafael G. Amado

July 30, 2019

\_\_\_\_\_  
Date

EXHIBIT A

Employee Confidential Information and Invention Assignment Agreement

## EMPLOYEE CONFIDENTIAL INFORMATION AND INVENTION ASSIGNMENT AGREEMENT

In consideration of my employment or continued employment by Allogene Therapeutics, Inc., its direct and indirect subsidiaries, parents, affiliates, predecessors, successors and assigns (together "**Company**"), and the compensation and benefits provided to me now and during my employment with Company, I hereby enter into this Employee Confidential Information and Invention Assignment Agreement (the "**Agreement**"), which will be deemed effective as of the first day of my employment with the Company:

### 1. CONFIDENTIAL INFORMATION PROTECTIONS.

**1.1 Recognition of Company's Rights; Nondisclosure.** I understand and acknowledge that my employment by Company creates a relationship of confidence and trust with respect to Company's Confidential Information (as defined below) and that Company has a protectable interest therein. At all times during and after my employment, I will hold in confidence and will not disclose, use, lecture upon, or publish any of Company's Confidential Information, except as such disclosure, use or publication may be required in connection with my work for Company, or unless an officer of Company expressly authorizes such disclosure. I will obtain Company's written approval before publishing or submitting for publication any material (written, oral, or otherwise) that discloses and/or incorporates any Confidential Information. I hereby assign to Company any rights I may have or acquire in such Confidential Information and recognize that all Confidential Information shall be the sole and exclusive property of Company and its assigns. I will take all reasonable precautions to prevent the inadvertent accidental disclosure of Confidential Information. Notwithstanding the foregoing, pursuant to 18 U.S.C. Section 1833(b), I shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that: (1) is made in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney, and solely for the purpose of reporting or investigating a suspected violation of law; or (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal.

**1.2 Confidential Information.** The term "**Confidential Information**" shall mean any and all confidential knowledge, data or information of Company. By way of illustration but not limitation, "**Confidential Information**" includes (a) trade secrets, inventions, mask works, ideas, processes, formulas, software in source or object code versions, data, programs, other works of authorship, know-how, improvements, discoveries, developments, designs and techniques and any other proprietary technology and all Intellectual Property Rights therein (collectively, "**Inventions**"); (b) information regarding research, development, new products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, margins, discounts, credit terms, pricing and billing policies, quoting procedures, methods of obtaining business, forecasts, future plans and potential strategies, financial projections and business

strategies, operational plans, financing and capital-raising plans, activities and agreements, internal services and operational manuals, methods of conducting Company business, suppliers, and supplier information, and purchasing; (c) information regarding customers and potential customers of Company, including customer lists, names, representatives, their needs or desires with respect to the types of products or services offered by Company, proposals, bids, contracts and their contents and parties, the type and quantity of products and services provided or sought to be provided to customers and potential customers of Company and other non-public information relating to customers and potential Customers; (d) information regarding any of Company's business partners and their services, including names; representatives, proposals, bids, contracts and their contents and parties, the type and quantity of products and services received by Company, and other non-public information relating to business partners; (e) information regarding personnel, employee lists, compensation, and employee skills; and (f) any other non-public information which a competitor of Company could use to the competitive disadvantage of Company. Notwithstanding the foregoing, it is understood that, at all such times, I am free to use information which is generally known in the trade or industry through no breach of this Agreement or other act or omission by me. Further, notwithstanding the foregoing or anything to the contrary in this Agreement or any other agreement between the Company and me, nothing in this Agreement shall limit my right to discuss my employment or report possible violations of law or regulation with any federal government agency or similar state or local agency or to discuss the terms and conditions of my employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act or to the extent that such disclosure is protected under the applicable provisions of law or regulation.

**1.3 Third Party Information.** I understand, in addition, that Company has received and in the future will receive from third parties their confidential and/or proprietary knowledge, data or information ("**Third Party Information**") subject to a duty on Company's part to maintain the confidentiality of such information and to use it only for certain limited purposes. During my employment and thereafter, I will hold Third Party Information in confidence and will not disclose to anyone (other than Company personnel who need to know such information in connection with their work for Company) or use, except in connection with my work for Company, Third Party Information unless expressly authorized by an officer of

Company in writing.

**1.4 No Improper Use of Information of Prior Employers and Others.** During my employment by Company, I will not improperly use or disclose confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto the premises of Company any unpublished documents or any property belonging to any former employer or any other person to whom I have an obligation of confidentiality unless consented to in writing by that former employer or person.

## 2. ASSIGNMENTS OF INVENTIONS.

**2.1 Definitions.** As used in this Agreement, the term “**Intellectual Property Rights**” means all trade secrets, Copyrights, trademarks, mask work rights, patents and other intellectual property rights recognized by the laws of any jurisdiction or country; the term “**Copyright**” means the exclusive legal right to reproduce, perform, display, distribute and make derivative works of a work of authorship (as a literary, musical, or artistic work) recognized by the laws of any jurisdiction or country; and the term “**Moral Rights**” means all paternity, integrity, disclosure, withdrawal, special and any other similar rights recognized by the laws of any jurisdiction or country.

**2.2 Excluded Inventions and Other Inventions.** Attached hereto as **Attachment 1** is a list describing all existing Inventions, if any, that may relate to Company’s business or actual or demonstrably anticipated research or development and that were made by me or acquired by me prior to the commencement of my employment with, and which are not to be assigned to, Company (“**Excluded Inventions**”). If no such list is attached, I represent and agree that it is because I have no rights in any existing Inventions that may relate to Company’s business or actual or demonstrably anticipated research or development. For purposes of this Agreement, “**Other Inventions**” means Inventions in which I have or may have an interest, as of the commencement of my employment or thereafter, other than Company Inventions (defined below) and Excluded Inventions. I acknowledge and agree that if I use any Excluded Inventions or any Other Inventions in the scope of my employment, or if I include any Excluded Inventions or Other Inventions in any product or service of Company, or if my rights in any Excluded Inventions or Other Inventions may block or interfere with, or may otherwise be required for, the exercise by Company of any rights assigned to Company under this Agreement, I will immediately so notify Company in writing. Unless Company and I agree otherwise in writing as to particular Excluded Inventions or Other Inventions, I hereby grant to Company, in such circumstances (whether or not I give Company notice as required above), a non-exclusive, perpetual, transferable, fully-paid and royalty-free, irrevocable and worldwide license, with

rights to sublicense through multiple levels of sublicensees, to reproduce, make derivative works of, distribute, publicly perform, and publicly display in any form or medium, whether now known or later developed, make, have made, use, sell, import, offer for sale, and exercise any and all present or future rights in, such Excluded Inventions and Other Inventions. To the extent that any third parties have rights in any such Other Inventions, I hereby represent and warrant that such third party or parties have validly and irrevocably granted to me the right to grant the license stated above.

**2.3 Assignment of Company Inventions.** Inventions assigned to Company, or to a third party as directed by Company pursuant to Section 2.6, are referred to in this Agreement as “**Company Inventions.**” Subject to Section 2.4 (Unassigned or Nonassignable Inventions) and except for Excluded Inventions set forth in **Attachment 1** and Other Inventions, I hereby assign to Company all my right, title, and interest in and to any and all Inventions (and all Intellectual Property Rights with respect thereto) made, conceived, reduced to practice, or learned by me, either alone or with others, during the period of my employment by Company. To the extent required by applicable Copyright laws, I agree to assign in the future (when any copyrightable Inventions are first fixed in a tangible medium of expression) my Copyright rights in and to such Inventions. Any assignment of Company Inventions (and all Intellectual Property Rights with respect thereto) hereunder includes an assignment of all Moral Rights. To the extent such Moral Rights cannot be assigned to Company and to the extent the following is allowed by the laws in any country where Moral Rights exist, I hereby unconditionally and irrevocably waive the enforcement of such Moral Rights, and all claims and causes of action of any kind against Company or related to Company’s customers, with respect to such rights. I further acknowledge and agree that neither my successors-in-interest nor legal heirs retain any Moral Rights in any Company Inventions (and any Intellectual Property Rights with respect thereto).

**2.4 Unassigned or Nonassignable Inventions.** I recognize that this Agreement will not be deemed to require assignment of any Invention that is covered under California Labor Code section 2870(a) (the “**Specific Inventions Law**”), as detailed on **Attachment 2**.

**2.5 Obligation to Keep Company Informed.** During the period of my employment and for one (1) year after termination of my employment, I will promptly and fully disclose to Company in writing all Inventions authored, conceived, or reduced to practice by me, either alone or jointly with others. In addition, I will promptly disclose to Company all patent applications filed by me or on my behalf within one (1) year after termination of employment. At the time of each such disclosure, I will advise Company in writing of any Inventions that I believe fully qualify for protection under the provisions of the Specific Inventions Law; and I will at that

time provide to Company in writing all evidence necessary to substantiate that belief. Company will keep in confidence and will not use for any purpose or disclose to third parties without my consent any confidential information disclosed in writing to Company pursuant to this Agreement relating to Inventions that qualify fully for protection under the Specific Inventions Law. I will preserve the confidentiality of any Invention that does not fully qualify for protection under the Specific Inventions Law.

**2.6 Government or Third Party.** I agree that, as directed by Company, I will assign to a third party, including without limitation the United States, all my right, title, and interest in and to any particular Company Invention.

**2.7 Ownership of Work Product.**

(a) I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment and which are protectable by Copyright are "works made for hire," pursuant to United States Copyright Act (17 U.S.C., Section 101).

(b) I agree that Company will exclusively own all work product that is made by me (solely or jointly with others) within the scope of my employment, and I hereby irrevocably and unconditionally assign to Company all right, title, and interest worldwide in and to such work product. I understand and agree that I have no right to publish on, submit for publishing, or use for any publication any work product protected by this Section, except as necessary to perform services for Company.

**2.8 Enforcement of Intellectual Property Rights and Assistance.** I will assist Company in every proper way to obtain, and from time to time enforce, United States and foreign Intellectual Property Rights and Moral Rights relating to Company Inventions in any and all countries. To that end I will execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Intellectual Property Rights and the assignment thereof. In addition, I will execute, verify and deliver assignments of such Intellectual Property Rights to Company or its designee, including the United States or any third party designated by Company. My obligation to assist Company with respect to Intellectual Property Rights relating to such Company Inventions in any and all countries will continue beyond the termination of my employment, but Company will compensate me at a reasonable rate after my termination for the time actually spent by me at Company's request on such assistance. In the event Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in this paragraph, I hereby irrevocably designate and appoint Company and its duly authorized officers and agents as my agent and attorney in fact, which appointment is coupled with an interest, to act for

and in my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Intellectual Property Rights assigned under this Agreement to Company.

**2.9 Incorporation of Software Code.** I agree that I will not incorporate into any Company software or otherwise deliver to Company any software code licensed under the GNU General Public License or Lesser General Public License or any other license that, by its terms, requires or conditions the use or distribution of such code on the disclosure, licensing, or distribution of any source code owned or licensed by Company except in strict compliance with Company's policies regarding the use of such software.

**3. RECORDS.** I agree to keep and maintain adequate and current records (in the form of notes, sketches, drawings and in any other form that is required by Company) of all Confidential Information developed by me and all Company Inventions made by me during the period of my employment at Company, which records will be available to and remain the sole property of Company at all times.

**4. DUTY OF LOYALTY DURING EMPLOYMENT.** I agree that during the period of my employment by Company I will not, without Company's express written consent, directly or indirectly engage in any employment or business activity which is directly or indirectly competitive with, or would otherwise conflict with, my employment by Company.

**5. NO SOLICITATION OF EMPLOYEES, CONSULTANTS, OR CONTRACTORS.** I agree that during the period of my employment and for the one (1) year period after the date my employment ends for any reason, including but not limited to voluntary termination by me or involuntary termination by Company, I will not, as an officer, director, employee, consultant, owner, partner, or in any other capacity, either directly or through others, except on behalf of Company solicit, induce, encourage, or participate in soliciting, inducing or encouraging any employee, consultant, or independent contractor of Company to terminate his, her or its relationship with Company, even if I did not initiate the discussion or seek out the contact.

**6. REASONABLENESS OF RESTRICTIONS.**

**6.1** I agree that I have read this entire Agreement and understand it. I agree that this Agreement does not prevent me from earning a living or pursuing my career. I agree that the restrictions contained in this Agreement are reasonable, proper, and necessitated by Company's legitimate business interests. I represent and agree that I am entering into this Agreement



freely and with knowledge of its contents with the intent to be bound by the Agreement and the restrictions contained in it.

**6.2** In the event that a court or arbitrator finds this Agreement, or any of its restrictions, to be ambiguous, unenforceable, or invalid, Company and I agree that the court or arbitrator will read the Agreement as a whole and interpret the restriction(s) at issue to be enforceable and valid to the maximum extent allowed by law.

**6.3** If the court or arbitrator declines to enforce this Agreement in the manner provided in subsection 6.2, Company and I agree that this Agreement will be automatically modified to provide Company with the maximum protection of its business interests allowed by law and I agree to be bound by this Agreement as modified.

**7. NO DISPARAGEMENT.** I agree that, during my employment with the Company and after the termination of my employment for any reason, I will not disparage the Company, its officers, directors, managers, employees, consultants, shareholders, or agents, in any manner likely to be harmful to it or their business, business reputation or personal reputation. Notwithstanding the foregoing, nothing in this Agreement shall prohibit me from making truthful statements or disclosures required by applicable law, regulation or legal process; or requesting or receiving confidential legal advice. Nothing in this Agreement shall limit my right to make truthful statements in the proper performance of my job duties for the Company, discuss my employment, or report possible violations of law or regulation with the SEC, EEOC, DOL, NLRB, OSHA or other federal government agency or similar state or local agency, or to discuss the terms and conditions of my employment with others to the extent expressly permitted by Section 7 of the NLRA, or to the extent that such disclosure is protected under the applicable provisions of law or regulation, including but not limited to "whistleblower" statutes or other similar provisions that protect such disclosure.

**8. NO CONFLICTING AGREEMENT OR OBLIGATION.** I represent that my employment by Company does not and will not breach any agreement with any former employer or third party, including any noncompete agreement or any agreement to keep in confidence or refrain from using information acquired by me prior to my employment by Company. I further represent that I have not entered into, and will not enter into, any agreement, either written or oral, in conflict with my obligations under this Agreement.

**9. RETURN OF COMPANY PROPERTY.** Subject to the nondisclosure requirements of Section 1.1 above, upon termination of my employment or upon Company's request at any other time, I will deliver to Company any and all of Company's property and equipment and any and all drawings, notes, memoranda, specifications, devices, formulas and documents, together with all copies thereof, and any other

material containing or disclosing any Company Inventions, Third Party Information or Confidential Information of Company. I agree that I will not copy, delete, or alter any information contained upon my Company computer or Company equipment before I return it to Company. In addition, if I have used any personal computer, server, or e-mail system to receive, store, review, prepare or transmit any Company information, including but not limited to, Confidential Information, I agree to provide the Company access to any such personal systems as reasonably requested to search for, copy and/or delete such information, and upon my employment termination I agree to provide Company with a computer-useable copy of all such Confidential Information and then permanently delete and expunge such Confidential Information from those systems; and I agree to provide Company access to my system as reasonably requested to verify that the necessary copying and/or deletion is completed. I further agree that any property situated on Company's premises and owned by Company, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company's personnel at any time with or without notice. Prior to leaving, I will cooperate with Company in attending an exit interview and completing and signing Company's Termination Certificate; however, my failure to sign and deliver the Termination Certificate shall in no way diminish my continuing obligations under this Agreement.

## **10. LEGAL AND EQUITABLE REMEDIES.**

**10.1** I agree that it may be impossible to assess the damages caused by my violation of this Agreement or any of its terms. I agree that any threatened or actual violation of this Agreement or any of its terms will constitute immediate and irreparable injury to Company, and Company will have the right to enforce this Agreement and any of its provisions by injunction, specific performance or other equitable relief, without bond and without prejudice to any other rights and remedies that Company may have for a breach or threatened breach of this Agreement.

**10.2** In the event Company enforces this Agreement through a court or arbitration order, I agree that the restrictions of Sections 5 will remain in effect for a period of twelve (12) months from the effective date of the order enforcing the Agreement.

**11. NOTICES.** Any notices required or permitted under this Agreement will be given to Company at its headquarters location at the time notice is given, and to me at my address as listed on Company payroll, or at such other address as Company or I may designate by written notice to the other. Notice will be effective upon receipt or refusal of delivery. If delivered by certified or registered mail, notice will be considered to have been given five (5) business days after it was mailed, as evidenced by the postmark. If delivered by courier or express mail service, notice will be considered to

have been given on the delivery date reflected by the courier or express mail service receipt.

**12. NOTIFICATION OF NEW EMPLOYER.** If I leave the employ of Company, I consent to the notification of my new employer of my rights and obligations under this Agreement, by Company providing a copy of this Agreement or otherwise.

**13. GENERAL PROVISIONS.**

**13.1 Governing Law.** This Agreement will be governed by and construed according to the laws of the State of California as such laws are applied to agreements entered into and to be performed entirely within California between California residents.

**13.2 Severability.** In case any one or more of the provisions, subsections, or sentences contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect the other provisions of this Agreement, and this Agreement will be construed as if such invalid, illegal or unenforceable provision had never been contained in this Agreement. If moreover, any one or more of the provisions contained in this Agreement will for any reason be held to be excessively broad as to duration, geographical scope, activity or subject, it will be construed by limiting and reducing it, so as to be enforceable to the extent compatible with the applicable law as it will then appear.

**13.3 Successors and Assigns.** This Agreement is for my benefit and the benefit of Company, its successors, assigns, parent corporations, direct and indirect subsidiaries, affiliates, and purchasers, and will be binding upon my heirs, executors, administrators and other legal representatives.

**13.4 Survival.** This Agreement shall survive the termination of my employment, regardless of the reason, and the assignment of this Agreement by Company to any successor in interest or other assignee.

**13.5 Employment At-Will.** I agree and understand that

nothing in this Agreement will change my at-will employment status or confer any right with respect to continuation of employment by Company, nor will it interfere in any way with my right or Company's right to terminate my employment at any time, with or without cause or advance notice.

**13.6 Waiver.** No waiver by Company of any breach of this Agreement will be a waiver of any preceding or succeeding breach. No waiver by Company of any right under this Agreement will be construed as a waiver of any other right. Company will not be required to give notice to enforce strict adherence to all terms of this Agreement.

**13.7 Export.** I agree not to export, reexport, or transfer, directly or indirectly, any U.S. technical data acquired from Company or any products utilizing such data, in violation of the United States export laws or regulations.

**13.8 Advice of Counsel.** I ACKNOWLEDGE THAT, IN EXECUTING THIS AGREEMENT, I HAVE HAD THE OPPORTUNITY TO SEEK THE ADVICE OF INDEPENDENT LEGAL COUNSEL, AND I HAVE READ AND UNDERSTOOD ALL OF THE TERMS AND PROVISIONS OF THIS AGREEMENT. THIS AGREEMENT WILL NOT BE CONSTRUED AGAINST ANY PARTY BY REASON OF THE DRAFTING OR PREPARATION OF THIS AGREEMENT.

**13.9 Entire Agreement.** The obligations pursuant to Sections 1 and 2 of this Agreement will apply to any time during which I was previously engaged, or am in the future engaged, by Company as a consultant (except Subsection 2.4 and 2.7(a)) or employee if no other agreement governs nondisclosure and assignment of inventions during such period. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter of this Agreement and supersedes and merges all prior discussions between us. No modification or amendment to this Agreement, will be effective unless in writing and signed by the party to be charged. Any subsequent change or changes in my duties, salary or compensation will not affect the validity or scope of this Agreement.

This Agreement shall be effective as of the first day of my employment with the Company.

**EMPLOYEE:  
I HAVE READ, UNDERSTAND, AND ACCEPT THIS AGREEMENT AND HAVE BEEN GIVEN THE OPPORTUNITY TO REVIEW IT WITH INDEPENDENT LEGAL COUNSEL. I HAVE ALSO COMPLETELY FILLED OUT ATTACHMENT 1.**

**COMPANY:  
ACCEPTED AND AGREED:**

\_\_\_\_\_  
/s/ Rafael Amado  
(Signature)  
By: Rafael Amado  
Title: EVP of R&D and CMO  
Date: July 30, 2019  
Address: \_\_\_\_\_

\_\_\_\_\_  
/s/ Veer Bhavnagri  
(Signature)  
By: Veer Bhavnagri  
Title: General Counsel  
Date: July 26, 2019  
Address: 210 E Grand Avenue, South San Francisco, CA 94080

**ATTACHMENT 1**

**PRIOR INVENTIONS**

**TO:** Allogene Therapeutics, Inc.  
**FROM:**  
**DATE:**  
**SUBJECT:** Prior Inventions

1. Except as listed in Section 2 below, the following is a complete list of all inventions or improvements relevant to the subject matter of my employment by Allogene Therapeutics, Inc. ("**Company**") that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by Company:

- No inventions or improvements
- See below:

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Additional sheets attached.

2. Due to a prior confidentiality agreement, I cannot complete the disclosure under Section 1 above with respect to inventions or improvements generally listed below, the intellectual property rights and duty of confidentiality with respect to which I owe to the following party(ies):

	<b>Invention or Improvement</b>	<b>Party(ies)</b>	<b>Relationship</b>
1.	<hr/>	<hr/>	<hr/>
2.	<hr/>	<hr/>	<hr/>
3.	<hr/>	<hr/>	<hr/>

Additional sheets attached.

**ATTACHMENT 2**

**LIMITED EXCLUSION NOTIFICATION**

This is to notify you in accordance with Section 2872 of the California Labor Code that the foregoing Agreement between you and Company does not require you to assign or offer to assign to Company any Invention that you develop entirely on your own time without using Company's equipment, supplies, facilities or trade secret information, except for those Inventions that either:

- (a) Relate at the time of conception or reduction to practice to Company's business, or actual or demonstrably anticipated research or development; or
- (b) Result from any work performed by you for Company.

To the extent a provision in the foregoing Agreement purports to require you to assign an Invention otherwise excluded from the preceding paragraph, the provision is against the public policy of this state and is unenforceable.

This limited exclusion does not apply to any patent or Invention covered by a contract between Company and the United States or any of its agencies requiring full title to such patent or Invention to be in the United States.

EXHIBIT B

Arbitration Agreement

### **Arbitration Agreement**

I recognize that disputes may arise between Allogene Therapeutics, Inc. (the "Company") and me during or following my employment with the Company, and that those disputes may or may not be related to my employment. The parties understand and agree that by entering into this Arbitration Agreement (the "Agreement"), they anticipate gaining the benefits of a speedy, impartial, final and binding dispute-resolution procedure.

The Company and I mutually consent to the resolution by arbitration of all claims or controversies ("claims"), past, present or future, whether or not arising out of my employment (or its termination), that the Company may have against me or that I (and no other party) may have against (1) the Company; (2) the Company's officers, directors, employees or agents in whatever capacity; (3) the Company's parent, subsidiary and affiliated entities; (4) the Company's benefit plans or the plans' sponsors, fiduciaries, administrators, affiliates and agents (except claims under an employee benefit or pension plan that specifies a different claims process; and/or (5) all successors and assigns of any of them. The Federal Arbitration Act (9 U.S.C., Sections 1-16) ("FAA") shall govern the interpretation, enforcement and all proceedings pursuant to this Agreement. To the extent that the Federal Arbitration Act is inapplicable, or held not to require arbitration of a particular claim or claims, the arbitration law of the state in which I work or last worked for the Company shall apply.

Arbitrable claims include, but are not limited to: claims for wages/other compensation due and any related claims; claims for breach of any contract or covenant (express or implied); tort claims; claims for retaliation; claims for harassment; claims for discrimination (including, but not limited to, race, sex, sexual orientation, religion, national origin, age, marital status, physical or mental disability or handicap, or medical condition); claims for benefits (except as noted above); and claims for violation of any federal, state, or other governmental law, statute, regulation, or ordinance. The following claims are not covered by this Agreement: claims for Workers' Compensation or Unemployment Insurance benefits; claims pending against the Company at the time I sign this Agreement in any forum; and claims that as a matter of law cannot be subject to arbitration.

**Both the Company and I hereby waive the right to a trial by jury or judge, or by administrative proceeding, for any claim or dispute covered by this Agreement.** Both the Company and I agree that neither of us shall initiate or prosecute any lawsuit in any way related to any claim covered by this Agreement to arbitrate, except that this Agreement does not prohibit the filing of or pursuit of relief through the following: (i) seeking temporary or preliminary injunction relief as is otherwise available by law, (ii) an administrative charge to any federal, state or local equal employment opportunity or fair employment practices agency, (iii) an administrative charge to the National Labor Relations Board, or (iv) any other charge filed with or communication to a federal, state or local government office, official or agency.

The arbitration will be held before a neutral arbitrator under the auspices of JAMS. The arbitration shall take place in the county (or comparable government unit) in which I am or was last employed by the Company, and, except as provided above, no dispute affecting my rights or responsibilities shall be adjudicated in any other venue or forum. The arbitration shall be held in accordance with its then-current Employment Arbitration Rules & Procedures (and no other JAMS rules), which are currently available at <http://www.jamsadr.com/rules-employment-arbitration>. I understand that the Company will provide me a written copy of those rules upon my request. The Arbitrator shall be either a retired judge, or an attorney who is experienced in employment law and licensed to practice law in the state in which the arbitration is convened (the "Arbitrator"), and shall be selected pursuant to the JAMS rules.

The Arbitrator shall apply the substantive law (and the law of remedies, if applicable) of the state in which the claim arose, or federal law, or both, as applicable to the claim(s) asserted. The Arbitrator is without jurisdiction to apply any different substantive law or law of remedies. The Federal Rules of Evidence shall apply. The Arbitrator shall have the power to award any types of legal or equitable relief that would be available under applicable law, shall have the authority to compel adequate discovery for the resolution of the dispute, and shall render an award and

written opinion, which shall include the factual and legal basis for the award. The arbitration decision shall be final and binding upon the parties.

**Questions regarding the enforceability, interpretation, scope, applicability or coverage of this Agreement (including whether an issue is subject to arbitration under this Agreement) shall be decided by the arbitrator.** Likewise, procedural questions which grow out of the dispute and bear on the final disposition are also matters for the arbitrator. Pursuant to the FAA, issues of contract formation and enforcement relating to this Agreement shall be governed by and decided under the internal laws of the State of California, without regard to conflict of law rules.

The Company will be responsible for paying any filing fee and the fees and costs of the Arbitrator. Each party shall pay in the first instance its own litigation costs and attorneys' fees, if any. However, if any party prevails on a claim which affords the prevailing party attorneys' fees and/or litigation costs, then the Arbitrator shall rule upon a motion for attorneys' fees and/or litigation costs under the same standards a court would apply under the law applicable to the claim(s) at issue.

To the maximum extent permitted by law, all claims, disputes, or causes of action under this Agreement, whether by me or the Company, must be brought in an individual capacity, and shall not be brought as a plaintiff (or claimant) or class member in any purported class, collective, or representative proceeding; **provided, however,** that this Agreement shall not apply to any representative action under the California Private Attorney General Act ("PAGA"). The arbitrator may not consolidate the claims of more than one person or entity, and may not preside over any form of representative, collective or class proceeding. If a court adjudicating a case involving the Company and me were to determine that there is an unwaivable right to bring a class action, any such action shall be brought only in court, and not in arbitration.

The Company and I agree that any arbitration, including, without limitation, discovery, documents produced and/or entered into evidence, hearings, legal briefing and the final award, shall be confidential, although the final award may be disclosed as necessary to confirm the award and obtain entry of a final judgment by a court of competent jurisdiction. The Company and I further agree that we will execute written confidentiality agreements in order to ensure arbitration remains confidential.

This Agreement shall survive the termination of my employment and the expiration of any benefit plan. It can only be revoked by a writing signed by both the Company's General Counsel and me specifically stating the intent to revoke this Agreement.

This is the complete agreement of the parties on the subjects covered, and supersedes any prior or contemporaneous oral or written understandings on the subjects addressed in this Agreement; provided, however, that if this Agreement is held to be unenforceable for any reason, then any prior arbitration agreement between the Company and me shall survive. No party is relying on any representations, oral or written, on the subject of the effect, enforceability or meaning of this Agreement, except as specifically set forth in this Agreement. This Agreement only can be modified in a written agreement signed by the parties.

If any provision of this Agreement is adjudged to be void or otherwise unenforceable, in whole or in part, such adjudication shall not affect the validity of the remainder of the agreement. All other provisions shall remain in full force and effect.

I understand that nothing in this agreement affects the at-will nature of my employment with the Company, and that my employment may be terminated by either party, at any time, with or without cause or advance notice.

I acknowledge that I have carefully read this Agreement, that I understand its terms and that I have entered into the Agreement voluntarily and not in reliance of any promises or representations by the Company other than those contained in the Agreement. I understand that by signing this Agreement, I am giving up my right to a jury trial. Finally, I further acknowledge that I have been given the opportunity to discuss this Agreement with my own legal counsel.

Dated: July 30, 2019

/s/ Rafael Amado

Employee Signature

Rafael Amado

Printed Name of Employee

Dated: July 26, 2019

COMPANY

By: /s/ Veer Bhavnagri

Veer Bhavnagri, General Counsel



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

## **COLLABORATION AND LICENSE Agreement**

This **Collaboration and License Agreement** (the “**Agreement**”), effective as of November 1, 2019 (the “**Effective Date**”), is made by and between **Allogene Therapeutics, Inc.**, a Delaware corporation with its principal place of business at 210 East Grand Ave., South San Francisco, CA 94080 (“**Allogene**”), and **Notch Therapeutics Inc.**, a corporation organized and existing under the laws of Ontario, Canada with registered address at 40 King Street West, Suite 2100, Toronto, Ontario M5H 3C2, Canada (“**Notch**”). Allogene and Notch are sometimes referred to herein individually as a “**Party**” and collectively as the “**Parties**.”

### **RECITALS**

**WHEREAS**, Allogene is a clinical-stage biotechnology company engaged in the research, development and commercialization of genetically engineered allogeneic T cell therapies for the treatment of cancer;

**WHEREAS**, Notch possesses certain technology and expertise relating to the use of pluripotent stem cells to manufacture T cell therapies;

**WHEREAS**, the Parties desire to collaborate in relation to research and development of the use of Notch’s proprietary technologies for generating and manufacturing cells of T cell or NK cell lineage in connection with Allogene’s cellular therapies, and potential commercialization of pharmaceutical products arising from such research and development activities for the treatment of certain hematological malignancies; and

**WHEREAS**, the Parties have entered into that certain stock purchase agreement of even date herewith;

**NOW, THEREFORE**, in consideration of the foregoing premises and the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

#### **1. DEFINITIONS**

1.1 “**Academic Use Rights**” means a non-exclusive license to Research Program Inventions granted by Notch or its Affiliate to a non-profit academic or research institution solely for such academic or research institution’s internal, non-commercial, non-clinical research. Such license shall not permit the publication or disclosure of any Research Program Invention or data related thereto without Allogene’s prior approval, not to be unreasonably withheld.

1.2 “**Affiliate**” means, as to a Party, any entity directly or indirectly controlling, controlled by or under common control with such Party, where “control” means (a) beneficial ownership of greater than fifty percent (50%) of the voting equity interests in such entity or (b) the possession, directly or indirectly, of the power to direct or cause the direction of the

management and policies of an entity, whether through the ownership of a voting equity interest, by contract or otherwise.

1.3 “**Alliance Manager**” has the meaning set forth in Section 3.1.

1.4 “**Allogene Background Technology**” means Background Technology Controlled by Allogene or its Affiliates.

1.5 “**Allogene Indemnitee**” has the meaning given in Section 11.1.

1.6 “**Allogene Technology**” means (a) Background Technology Controlled by Allogene, and (b) Allogene’s interest in any Research Program Inventions, excluding any Joint Technology.

1.7 “**Allogene Patents**” has the meaning given in Section 8.2.

1.8 “**Applicable Law**” means any and all applicable laws, ordinances, rules, directives, administrative circulars and regulations of any kind whatsoever of any Governmental Authority within the applicable jurisdiction.

1.9 “**Available**” and its cognates mean, with respect to a Target, that (a) Notch has not granted any Third Party any license, or option to acquire a license, under the Notch Technology to Exploit cellular therapy products Directed Against such Target (excluding licenses granted to service providers solely to provide services to Notch), or if Notch has granted such a license or option to acquire a license, such license or option to acquire a license has expired or terminated; and, if the requirement in clause (a) is met, (b) Notch, together with its Affiliates and any Third Party to which Notch had previously granted a license or option as described in clause (a), have not (i) expended an aggregate amount in excess of [\*\*\*] dollars (US\$[\*\*\*]) directly in the research and development of a cellular therapy product Directed Against such Target, or (ii) initiated any IND-enabling GLP toxicology studies for a cellular therapy product Directed Against such Target.

1.10 “**Background Technology**” means Patent Rights and Know-How (a) Controlled by a Party prior to the Effective Date or (b) Controlled by such Party during the Term, but not generated in the performance of the activities under this Agreement.

1.11 “**Bankruptcy Code**” has the meaning given in Section 12.4.

1.12 “**B-Cell Malignancies**” means the hematological malignancies or cancer that begins in blood-forming tissue, such as the bone marrow, or in the cells of the immune system and affect B cells. These include B-cell lymphomas and some leukemias. For clarity, B-Cell Malignancies shall for example not include Multiple Myeloma, chronic myelogenous leukemia, acute myelogenous leukemia, or T cell malignancies.

1.13 “**Biologics License Application**” or “**BLA**” means a Biologics License Application (as more fully described in U.S. 21 C.F.R. Part 601.20 or any successor regulation) and all amendments and supplements thereto submitted to the FDA, or any equivalent filing in a country or regulatory jurisdiction other than the U.S. with the applicable Regulatory Authority, or any similar application or submission for Regulatory Approval filed with a Regulatory Authority to obtain marketing approval for a biologic product in a country or in a group of countries.

1.14 **“Bi-Specific Product”** means a CAR Product which is directed against at least two Targets, both of which are Exclusive Targets. For clarity, a Bi-Specific Product may include a single CAR or two independent CARs, as long as they are intended to be expressed in the same T Cell or NK Cell.

1.15 **“Business Day”** means a day other than Saturday, Sunday or any day on which commercial banks located in the San Francisco, California, USA, or Toronto, Canada are authorized or obligated by Applicable Laws to close.

1.16 **“Calendar Quarter”** means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31; provided, however, that (a) the first Calendar Quarter of the Term or following First Commercial Sale of Product shall extend from the commencement of such period to the end of the first complete Calendar Quarter thereafter; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.

1.17 **“Calendar Year”** means (a) for the first year of the Term, the period beginning on the Effective Date and ending on December 31, 2019, (b) for each year of the Term thereafter, each successive period beginning on January 1 and ending twelve (12) consecutive calendar months later on December 31, and (c) for the last year of the Term, the period beginning on January 1 of the year in which the Agreement expires or terminates and ending on the effective date of expiration or termination of this Agreement.

1.18 **“CAR”** means a chimeric antigen receptor. For clarity, a CAR does not contain a TCR binding domain.

1.19 **“CAR Product”** means a pharmaceutical or biological product comprising an Engineered CAR Cell.

1.20 **“[\*\*\*]”** means the [\*\*\*], located at [\*\*\*].

1.21 **“CEOs”** means the Chief Executive Officer of Notch and the Chief Executive Officer of Allogene, or a named designee of either of the foregoing.

1.22 **“Cell Type”** means either a T Cell or an NK Cell.

1.23 **“Change of Control”** means with respect to a specified Party: (a) the acquisition, directly or indirectly, by a Person or “group” (whether in a single transaction or multiple transactions) of more than 50% of the voting power of such Party or of beneficial ownership of (or the right to acquire such beneficial ownership) of more than 50% of the outstanding equity or convertible securities of such Party (including by tender offer or exchange offer); (b) any merger, consolidation, share exchange, business combination, recapitalization, the sale of substantially all of assets of, or similar corporate transaction involving such Party (whether or not including one or more wholly owned subsidiaries of such Party), other than: (i) transactions involving solely such Party and/or one or more Affiliates, on the one hand, and one or more of such Party’s Affiliates, on the other hand, and/or (ii) transactions in which the stockholders of such Party immediately prior to such transaction hold at least 50% of the voting power of the surviving company or ultimate parent company of the surviving company; or (c) the adoption of a plan relating to the liquidation or dissolution of such Party. For purposes of this definition, the terms “group” and “beneficial ownership” has the meaning accorded in the U.S.

Securities Exchange Act of 1934 and the rules of the U.S. SEC thereunder in effect as of the Effective Date.

1.24 **“Claims”** means all liability, loss, damage, claim, injury, costs or expenses (including reasonable attorneys’ fees and expenses of litigation) of any kind arising from Third Party demands, claims, actions and proceedings (whether criminal or civil, in contract, tort or otherwise).

1.25 **“Collaboration Product”** means a T Cell or NK Cell created pursuant to the Research Program that expresses one or more CARs that are Directed Against one or more of the Exclusive Targets.

1.26 **“Collaboration Term”** has the meaning set forth in Section 2.1(h).

1.27 **“Combination Product”** has the meaning set forth in the definition of Net Sales.

1.28 **“Commercially Reasonable Efforts”** means, with respect to either Party in relation to this Agreement, such efforts (whether undertaken by such Party directly or by such Party’s Affiliates or Sublicensees) that are consistent with the efforts and resources used by a biopharmaceutical company of similar size and resources in the exercise of its commercially reasonable business practices relating to an exercise of a right or performance of an obligation under this Agreement, including the research, development, manufacture and commercialization of a pharmaceutical or biologic compound or product, as applicable, at a similar stage in its research, development or commercial life as the relevant Product, and that has commercial and market potential similar to the relevant Product, taking into account issues of intellectual property coverage, safety and efficacy, stage of development, product profile, competitiveness of Third Party products in the marketplace, supply chain, proprietary position, regulatory exclusivity, anticipated or approved labeling, present and future market and commercial potential, the likelihood of receipt of Regulatory Approval, profitability (including pricing and reimbursement status achieved or likely to be achieved), alternative therapies and legal issues.

1.29 **“Competing Products”** has the meaning set forth in Section 4.5(c).

1.30 **“Competitive Indication”** means B-Cell Malignancies and Multiple Myeloma.

1.31 **“Confidential Information”** has the meaning set forth in Section 9.1.

1.32 **“Control”** or **“Controlled”** means, with respect to any Know-How, Patent Rights or other Intellectual Property Rights, a Party has the legal authority or right (whether by ownership, license or otherwise) to grant a license, sublicense, access or right to use (as applicable) under such Know-How, Patent Rights, or other Intellectual Property Rights to the other Party on the terms and conditions set forth herein at the time of such grant, in each case without breaching the terms of any agreement with a Third Party. Notwithstanding the foregoing, Know-How, Patent Rights and other Intellectual Property Rights licensed by Notch under a New Notch Third Party In-License shall only be considered to be Controlled by Notch if Allogene elects, within [\*\*\*] days after notification thereof from Notch, to be bound by all terms and conditions thereof applicable to sublicensees thereunder (which terms and conditions shall be fully included in Notch’s notification to Allogene) and to pay the share of the license fees, milestone payments and royalties payable thereunder and reasonably allocated to such sublicense rights (which share that is paid by Allogene is subject to offset against Notch’s royalties to the

extent permitted under Section 6.9(b)) based on Allogene's sublicense rights thereunder relative to the rights thereunder retained by Notch, which share shall be negotiated by the Parties in good faith. For clarity, Notch shall provide such notification for election to Allogene as described in the preceding sentence for any Third Party license that includes any Intellectual Property Rights that would, if Allogene were to make the election set forth in the immediately prior sentence, fall within the definition of Notch Technology.

1.33 **“Cover”, “Covering” or “Covered”** means, with reference to a Patent Right and a product, composition, article of manufacture or method, that the manufacture, practice, use, offer for sale, sale or importation of such product, composition, article of manufacture or method, would infringe a Valid Claim of such Patent Right in the country in which such activity occurs without a license thereto (or ownership thereof) (or if such Patent Right is pending, would infringe such Valid Claim if it were to issue as then being prosecuted in good faith).

1.34 **“Development Milestone”** means any of the milestones described in Section 6.5.

1.35 **“Directed Against”** means, as used in connection with a Target, that the product or agent at issue is designed to interact or bind with such Target as its primary mechanism of action.

1.36 **“Dollars”** means the U.S. dollar, and “\$” shall be interpreted accordingly.

1.37 **“EMA”** means the European Medicines Agency, and any successor entity thereto.

1.38 **“Engineered CAR Cell”** means an engineered T Cell or NK Cell that expresses one or more CARs Directed Against a Target.

1.39 **“EU”** means all countries that are officially recognized as member states of the European Union at the relevant time.

1.40 **“Exclusive Target”** means (a) any Initial Target for which no Substitute Target has been selected by Allogene pursuant to Section 2.5, (b) any Substitute Target selected by Allogene pursuant to Section 2.5 to replace any Initial Target, and (c) any Optioned Target.

1.41 **“Exclusivity Term”** has the meaning set forth in Section 4.5(d).

1.42 **“Existing Notch Third Party In-License”** means [\*\*\*].

1.43 **“Exploit”** means to research, develop, make, have made, use, offer for sale, sell, import, export or otherwise exploit, or transfer possession of or title in, a product. Cognates of the word **“Exploit”** shall have correlative meanings.

1.44 **“Field”** means the treatment, prevention and palliation of all human and animal diseases and disorders, including, without limitation, the Competitive Indications.

1.45 **“First Commercial Sale”** means the first arm's length commercial sale for monetary value by Allogene, its Affiliates or Sublicensees of a Product in the Territory to a Third Party who is not a Sublicensee for end use or consumption by the general public of such Product in any country following the receipt of Regulatory Approval for such Product by Allogene, its Affiliates, or its Sublicensees; provided, however, that the following shall not constitute a First Commercial Sale: (a) any sale to an Affiliate or Sublicensee unless the Affiliate or Sublicensee is the last entity in the distribution chain of the Product; (b) any use of such Product in clinical

trials, non-clinical development activities or other development activities with respect to such Product by or on behalf of a Party, or disposal or transfer of such Product for a bona fide charitable purpose; and (c) compassionate use, in each case for which no payment is received by Allogene, its Affiliates or Sublicensees. For purposes of clarification, except as otherwise provided in the previous sentence, any first arm's length commercial sale to a distributor or wholesaler under any non-conditional sale arrangement would be a First Commercial Sale.

1.46 **"Full Time Equivalent"** or **"FTE"** means the equivalent of a full-time scientist's work time over a twelve (12)-month period (including customary vacations, sick days and holidays). The portion of an FTE year devoted by a scientist to the Research Program shall be determined by dividing the number of eight (8)-hour days during any twelve (12)-month period devoted by such employee to the Research Program by the total number of working days during such 12-month period.

1.47 **"Funding Minimum"** has the meaning set forth in Section 2.1.

1.48 **"FTE Rate"** means an annualized rate [\*\*\*] dollars (US\$[\*\*\*) per year for FTEs performing activities under the Research Plan.

1.49 **"GAAP"** means United States generally accepted accounting principles applied on a consistent basis.

1.50 **"Governmental Authority"** means any federal, state, national, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.51 **"Improvement"** means an advancement, modification, development or improvement.

1.52 **"Indemnify"** has the meaning given in Section 11.1.

1.53 **"Infringe"** or **"Infringement"** means any infringement as determined by Applicable Law, including, without limitation, direct infringement, contributory infringement or induced infringement.

1.54 **"Initial Target"** means any target set forth in Exhibit A.

1.55 **"Intellectual Property Rights"** means rights in and to all (a) U.S. and foreign patents and patent applications, including all provisional, utility, divisions, substitutions, continuations, continuations-in-part, reissues, re-examinations and extensions thereof, or inventor certificates, or equivalents thereof, (b) copyrights, whether registered or unregistered, (c) Know-How, (d) software, (e) trademarks, service marks, trade names, trade dress, domain names and similar rights, including goodwill therein whether registered or not, and (f) any other intellectual or other proprietary rights of any kind now known or hereafter recognized in any jurisdiction, including the right to bring a claim with respect to any of the foregoing for past, present or future infringement, and any applications or registrations thereof.

1.56 **“Inventions”** means any process, method, composition, formulation, article of manufacture, method, discovery or finding, whether or not patentable or copyrightable, including all rights, title and interest in and to the Intellectual Property Rights therein.

1.57 **“iPSCs”** means induced pluripotent stem cells.

1.58 **“Joint Development Committee”** or **“JDC”** has the meaning set forth in Section 3.2.

1.59 **“Joint Know-How”** means the Know-How included in the Joint Technology.

1.60 **“Joint Patents”** means the Patent Rights included in the Joint Technology.

1.61 **“Joint Technology”** has the meaning given in Section 7.2.

1.62 **“Know-How”** means any information and materials, including discoveries, improvements, modifications, processes, techniques, methods, assays, designs, protocols, formulas, data, databases, know-how and trade secrets (in each case, patentable, copyrightable or otherwise), but excluding any of the foregoing to the extent claimed by any issued Patent Right.

1.63 **“Materials”** has the meaning set forth in Section 2.3.

1.64 **“Member”** has the meaning set forth in Section 3.2.

1.65 **“Multiple Myeloma”** means a cancer that forms in a type of white blood cell called a plasma cell.

1.66 **“Necessary”** has the meaning set forth in Section 6.9(a).

1.67 **“Negotiation Period”** has the meaning set forth in Section 2.7(c).

1.68 **“Net Sales”** means, with respect to any Product, the gross amounts invoiced by Allogene, its Affiliates and Sublicensees (each, a **“Selling Party”**) to Third Party customers in an arm’s length transaction for sales of such Product, less the following deductions actually incurred, allowed, taken, paid, accrued or allocated in its financial statements in accordance with GAAP (as applicable to the Selling Party), for:

(a) discounts (including trade, quantity and cash discounts) actually allowed, cash and non-cash coupons, retroactive price reductions, and charge-back payments and rebates granted to any Third Party (including to Governmental Authorities, purchasers, reimbursers, customers, distributors, wholesalers, and group purchasing and managed care organizations or entities (and other similar entities and institutions));

(b) credits or allowances, if any, on account of price adjustments, recalls, claims, damaged goods, rejections or returns of items previously sold (including Product returned in connection with recalls or withdrawals) and amounts written off by reason of uncollectible debt; provided, that if the debt is thereafter paid, the corresponding amount shall be added to the Net Sales of the period during which it is paid;

(c) rebates (or their equivalent), administrative fees, chargebacks and retroactive price adjustments and any other similar allowances granted by a Selling Party (including to Governmental Authorities, purchasers, reimbursers, customers, distributors,

wholesalers, and group purchasing and managed care organizations and entities (and other equivalent entities and institutions)) which effectively reduce the selling price or gross sales of the Product, as well as costs of distribution and wholesale;

(d) insurance, customs charges, freight, postage, shipping, handling, and other transportation costs incurred by a Selling Party in shipping Product to a Third Party; and

(e) import taxes, export taxes, excise taxes, sales tax, value-added taxes, consumption taxes, duties or other taxes levied on, absorbed, determined and/or imposed with respect to such sales (excluding income or net profit taxes or franchise taxes of any kind).

(f) Sales of Product(s) between or among Allogene and its Affiliates, licensees or sublicensees shall be excluded from the computation of Net Sales and no payments shall be payable on such sales except where such Affiliates, licensees or sublicensees are end users.

For the avoidance of doubt, sales of a Product for an invoice price less than or equal to Allogene's or its applicable Affiliate's, licensee's or sublicensee's cost of goods sold (reasonably determined consistent with GAAP and customary manufacturing cost accounting principles) for (x) use in conducting clinical trials of such Product in a country in order to obtain the Regulatory Approval of such Product in such country or (y) any compassionate use or named patient sales shall be excluded from Net Sales calculations for all purposes.

If a Product is sold in combination with other pharmaceutical or biologic active ingredients that are not themselves Products (collectively, the "**Combination Components**"), and taken together (whether co-formulated, co-packaged or for co-administration) with the Product, the "**Bundled Product**") for a single price, the Net Sales applicable to such transaction will be the product of (i) Net Sales of the Bundled Product calculated as above (i.e., calculated as for a non-Bundled Product) and (ii) the fraction  $(A/(A+B))$ , where:

"A" is the gross invoice price in such country of the Product as the sole therapeutically active ingredient; and

"B" is the gross invoice price in such country of all of the Combination Components contained in the Bundled Product.

If "A" or "B" cannot be determined by reference to sales other than in connection with a Bundled Product as described above, then Net Sales will be calculated as above, but the gross invoice price in the above equation shall be the relative value contributions of the Product and Combination Components to the Bundled Product gross invoice price, as reasonably determined by the Parties in good faith. Notwithstanding the foregoing and solely for calculating Net Sales under this Agreement, if the Combination Component is a pre-conditioning antibody, the Parties shall assign relative value contributions of the Product and such Combination Component to the Bundled Product gross invoice price, as reasonably determined by the Parties in good faith.

1.69 "**New Notch Third Party In-License**" means any license of Third Party Know-How, Patent Rights or other Intellectual Property Rights entered into by Notch after the Effective Date.



1.70 **“NK Cell”** means a natural killer cell, or an innate lymphocyte that does not express a TCR, and recognizes target cells through a balance of signals from activating and inhibitory receptors. For clarity, NK Cells do not include T Cells. NK cells may express CD56 and CD16.

1.71 **“Non-Publishing Party”** has the meaning given in Section 9.7(a).

1.72 **“Notch Background Technology”** means Background Technology Controlled by Notch or its Affiliates.

1.73 **“Notch Indemnitee”** has the meaning given in Section 11.1.

1.74 **“Notch Know-How”** means all Know-How that is (a) Controlled by Notch or its Affiliates as of the Effective Date or during the Term, (b) solely with respect to such Know-How arising after the Collaboration Term, is directly related to any Notch Technology utilized in the Research Program (or to any Notch Technology that existed during the Collaboration Term and was suitable for use in the Research Program) and (c) necessary or useful for the Exploitation of any CAR Product Directed Against one or more Exclusive Targets, including, to the extent necessary or useful, methods for (i) generating progenitor T Cells from donor material; (ii) generating and manufacturing cells of the T Cell lineage, including mature T Cells, hematopoietic stem cells, embryonic stem cells and/or iPSCs via a soluble or insoluble, bead-based system; and (iii) generating and manufacturing cells of the NK Cell lineage. Notch Know-How includes Notch’s interest in the Joint Know-How.

1.75 **“Notch Microbeads”** means a surface, such as a microbead, which creates an engineered thymic niche for three-dimensional presentation of immobilized proteins, such as delta-like ligand 4 and VCAM-1, in suspension cultures in order to instruct expedite progenitor and mature T-Cell differentiation from stem cells, such as hematopoietic or induced pluripotent stem cells.

1.76 **“Notch Microbead Technology”** means all Know-How and Patent Rights Controlled by Notch during the Term that relate to the production or use, as produced or used by or on behalf of Notch, of Notch Microbeads for the Exploitation of CAR Products directed to one or more Exclusive Targets, including the Patents and Know-How described in Exhibit B.

1.77 **“Notch Patents”** means any Patent Right that is Controlled by Notch or its Affiliates as of the Effective Date or during the Term, and Covers the Exploitation of any CAR Product Directed Against one or more Exclusive Targets. Notch Patents existing as of the Effective Date are listed in Exhibit C. Notch Patents include Notch’s interest in Joint Patents.

1.78 **“Notch Technology”** means the Notch Know-How and Notch Patents, and includes the Notch Microbead Technology.

1.79 **“Notch Third Party In-Licenses”** means (a) the Existing Notch Third Party In-License and (b) any New Notch Third Party In-License pursuant to which Allogene receives a sublicense of rights under this Agreement.

1.80 **“Optioned Target”** has the meaning set forth in Section 2.6(a).

1.81 **“Patent Rights”** means all US patents and provisional and non-provisional patent applications (which for the purpose of this Agreement shall be deemed to include certificates of

invention and applications for certificates of invention), including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, revalidations, extensions, registrations, patent term extensions, patent term adjustments, and supplemental protection certificates and the like of any such patents and patent applications, and any and all foreign equivalents of the foregoing.

1.82 “**Person**” means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

1.83 “**Phase 1 Clinical Trial**” means a human clinical trial of a CAR Product, the principal purpose of which is a preliminary determination of safety, pharmacokinetics, and pharmacodynamic parameters in healthy individuals or patients, as described in 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

1.84 “**Phase 2 Clinical Trial**” means a human clinical trial of a CAR Product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(b) and is intended to explore a variety of doses, dose response, and duration of effect, and to generate evidence of clinical safety and effectiveness for a particular therapeutic indication or therapeutic indications in a target patient population, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

1.85 “**Phase 3 Clinical Trial**” means a human clinical trial of a CAR Product in any country that would satisfy the requirements of U.S. 21 C.F.R. Part 312.21(c) and is intended to (a) establish that the Product is safe and efficacious for its intended use, (b) define contraindications, warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed, and (c) support Regulatory Approval for such Product, or a similar clinical study prescribed by the relevant Regulatory Authorities in a country other than the United States.

1.86 “**Pivotal Clinical Trial**” means a Clinical Trial of a CAR Product in a sufficient number of subjects that satisfies both of the following ((a) and (b)):

(a) such Clinical Trial establishes that such CAR Product has an acceptable safety and efficacy profile for its intended use, and to determine warnings, precautions, and adverse reactions that are associated with such CAR Product in the dosage range to be prescribed, which Clinical Trial can be used to support Regulatory Approval of such CAR Product, or a similar clinical study prescribed by the United States, Canada or EMA; and

(b) such Clinical Trial may be a Phase 2 Clinical Trial or Phase 3 Clinical Trial that satisfies the requirements of any of the expedited development and review pathways available at the FDA or its foreign equivalent.

For the avoidance of doubt, a Clinical Trial may become a Pivotal Clinical Trial after the commencement of such trial based on the statistical significance of the data generated in such trial.

1.87 **“Prior Confidentiality Agreement”** means that certain non-disclosure agreement between the Parties dated January 11, 2019.

1.88 **“Product”** means a CAR Product that (a) expresses one or more CARs that are Directed Against one or more Exclusive Targets; and (b) the manufacture, use or sale of which is Covered by a Notch Patent or which was developed or manufactured through use of the Notch Technology. For clarity, a Product may be a Bispecific Product.

1.89 **“Product Infringement”** has the meaning given in Section 8.5(a).

1.90 **“Prosecuting and Maintaining”**, and its correlates, means preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof) and maintaining a Patent Right. For these purposes, “prosecution” shall include any post-grant proceeding including supplemental examination, post grant review proceeding, inter parties review proceeding, patent interference proceeding, opposition proceeding and reexamination.

1.91 **“PSCs”** means pluripotent stem cells.

1.92 **“Publishing Party”** has the meaning given in Section 9.7(a).

1.93 **“Regulatory Approval”** means all approvals, licenses, registrations, and authorizations by the Regulatory Authority necessary for the commercial sale of a CAR Product in the Field in a given country or regulatory jurisdiction, including pricing and reimbursement approval where required as part of obtaining such regulatory approval.

1.94 **“Regulatory Authority”** means any applicable Governmental Authority or other authority responsible for granting Regulatory Approvals for a CAR Product, including the FDA, the EMA and any corresponding national or regional regulatory authorities.

1.95 **“Regulatory Exclusivity”** means any exclusive marketing rights or data exclusivity rights conferred by any Regulatory Authority with respect to a Product, other than Patent Rights.

1.96 **“Remainder”** has the meaning set forth in Section 8.5(f).

1.97 **“Research Budget”** has the meaning set forth in Section 2.1(a).

1.98 **“Research Costs”** means (a) the costs of Notch FTEs performing activities under the Research Plan at the FTE Rate and otherwise without mark-up, (b) out-of-pocket costs directly incurred by Notch in performing activities under the Research Plan without mark-up, and (c) costs incurred by Notch for the Research Facility and cGMP manufacturing capacity in accordance with Section 2.2 without mark-up.

1.99 **“Research Milestones”** means any milestone described in Section 6.4.

1.100 **“Research Milestone 3”** means the first to be achieved of Research Milestone “T-3A” and Research Milestone “N-3A” as described in Section 6.4.

1.101 **“Research Plan”** has the meaning set forth in Section 2.1.

1.102 **“Research Program”** has the meaning set forth in Section 2.1.

1.103 “**Research Program Inventions**” means all Inventions discovered, conceived or created during the Collaboration Term by either Party or its Affiliates alone, or by the Parties jointly, in each case as a result of the activities conducted under the Research Plan.

1.104 “**ROFN Product**” has the meaning set forth in Section 2.7.

1.105 “**ROFN Target**” means any Target listed on Exhibit D; provided that Allogene may replace each Target listed on Exhibit D with an Available Target once. Allogene shall provide Notch with a written request for such replacement that names the new Target and describes its primary applicability to a Competitive Indication, and Notch shall respond in writing within [\*\*\*] days of receipt of such written request confirming the replacement or, if such Target is not Available, stating the new Target is not Available, in which case no replacement shall take place (for clarity, Notch shall not be required to disclose the identity of any Third Party that holds a license or option to such Target). For clarity, Allogene shall not have any ability to increase the number of aggregate Targets listed on Exhibit D or to replace any Target listed on Exhibit D with a Target that was previously an Exclusive Target.

1.106 “**Royalty Term**” has the meaning set forth in Section 6.10.

1.107 “**Rules**” has the meaning given in Section 13.2.

1.108 “**Selling Party**” has the meaning set forth in the definition of Net Sales.

1.109 “**Sublicensee(s)**” means any Third Party to which Allogene has granted a sublicense under this Agreement.

1.110 “**Substitute Target**” has the meaning set forth in Section 2.5(a).

1.111 “**Success Criteria**” has the meaning set forth in Section 2.1(a).

1.112 “**Supply Agreement**” has the meaning set forth in Section 5.3.

1.113 “**Target**” means an antigen expressed on or in a tumor cell.

1.114 “**T Cell**” means any lymphocytes that naturally contain a TCR and includes alpha beta T cells, gamma delta T cells, natural killer T cells and any other cell type naturally containing a TCR, whether variable or invariant. TCR may be genomically rearranged at alpha and beta loci, expressed on cell surface or intracellularly. T Cells may express both alpha and beta, only alpha or only beta chains, or neither.

1.115 “**TCR**” means a T cell receptor.

1.116 “**Term**” has the meaning set forth in Section 13.1.

1.117 “**Territory**” means worldwide.

1.118 “**Third Party**” means any person or entity other than a Party and its Affiliates and their respective employees, agents and representatives.

1.119 “**Third Party License**” has the meaning set forth in Section 6.9.

1.120 “**Useful**” has the meaning set forth in Section 6.9(a).

1.121 “**Valid Claim**” means (a) an issued claim of any issued patent within the Notch Patents that has not expired, or been revoked, cancelled, become abandoned or disclaimed, been declared invalid and/or unenforceable by a patent office or a decision or judgment of a court or other appropriate body of competent jurisdiction; and (b) a claim included in a pending patent application included in the Notch Patents that is being prosecuted in good faith and that has not been cancelled, withdrawn from consideration, finally determined to be unallowable by the patent office or applicable governmental authority (from which no appeal is or can be taken), or abandoned or disclaimed; provided, however, that, if a claim of a patent application has been pending for more than seven (7) years, such claim will not constitute a Valid Claim for the purposes of this Agreement unless and until a Patent issues with such claim; provided, further, that, for purposes of the foregoing proviso, any newly filed claim which claims priority to any earlier filed claim shall be considered pending for the same period of time as such earlier filed claim has been pending.

1.122 “**VAT**” has the meaning set forth in Section 6.13(b).

## 2 RESEARCH PROGRAM

### 2.1 Research Program.

(a) The Parties will conduct a research program directed to the use of the Notch Technology to discovery, generation and manufacturing of Products for oncology applications, pursuant to a research plan mutually agreed to by the Parties (such plan, the “**Research Plan**” and such program, the “**Research Program**”). The Research Plan shall include the following: (i) a timeline for the conduct of research activities, on an Exclusive Target-by-Exclusive Target basis as applicable (it being understood that, unless otherwise agreed by the Parties, the Research Plan shall be limited in scope to the activities for the Exclusive Target(s) specifically set forth in the Research Plan); (ii) the deliverables to be provided arising from such research activities; (iii) the personnel and other resources Notch is required to apply to the performance of the Research Program, which resources shall not exceed the Research Costs set forth in the Research Budget, (iv) any biological or chemical materials to be provided by a Party to the other Party in order for such Party to conduct its activities under the Research Plan (the providing Party’s “**Materials**”) and timing therefor; (v) any Know-How to be provided by a Party to the other Party in order for such Party to conduct its activities under the Research Plan and timing therefor; (vi) the criteria for determining whether each Research Milestone or Development Milestone has been successfully completed (with respect to each such milestone, the “**Success Criteria**”); (vii) Notch Affiliates, contractors and service providers expected to perform services pursuant to the Research Plan; and (viii) a budget for the Research Costs (the “**Research Budget**”), which, excluding the Research Costs incurred pursuant to Section 2.2, shall not exceed [\*\*\*] dollars (US\$[\*\*\*) for the duration of the Collaboration Term, unless otherwise agreed in writing by the Parties, or be less than [\*\*\*] dollars (US\$[\*\*\*) per Calendar Year (the “**Funding Minimum**”), pro-rated for partial Calendar Years, unless otherwise agreed in writing by the Parties. The initial Research Plan is set forth as Exhibit E to this Agreement. The Parties hereby agree that the T Cell-based Collaboration Products Directed Against any Target listed in Exhibit F to be researched, developed, manufactured and potentially commercialized shall utilize a chimeric antigen receptor construct produced using technology Allogene has licensed from Collectis SA.

(b) Notch shall provide reasonable, good faith, non-binding estimates for the Research Budget that is intended to fund Notch for the activities to be performed by Notch as set forth in the Research Plan and intended for the achievement of the goals set forth in the Research Plan, and shall provide supporting documentation therefor to Allogene upon request.

(c) Notch shall not be required to provide resources or to perform activities under the Research Plan the aggregate cost of which (including Notch FTEs at the FTE Rate, material and equipment purchases, costs pursuant to Section 2.2 below, and other Third-Party costs as specified in the Research Plan) exceeds the funding provided by Allogene for such activities.

(d) Subject to the foregoing provisions of this Section 2.1, each Party shall use Commercially Reasonable Efforts to conduct its respective obligations set forth in the Research Plan. For clarity, neither Party guarantees that any timeline, deliverables or Success Criteria will be achieved or provided, within the Research Budget or otherwise, and any failure by a Party to achieve any of the same shall not constitute a breach of this Agreement provided that such Party has fulfilled its obligations to use Commercially Reasonable Efforts as set forth in the preceding sentence.

(e) Each Party shall perform, and shall require that its applicable Affiliates, licensees, sublicensees and Third Party contractors perform, all research activities in a good scientific and ethical business manner and in compliance with the terms of this Agreement, and in compliance with all Applicable Laws. Any breaches of the foregoing by an Affiliate or Third Party shall, as between the Parties, be the responsibility of the Party that engaged such Affiliate or Third Party. No agreement between Notch and its Affiliates, licensees, sublicensees, or Third Party contractors that perform services pursuant to the Research Plan will conflict with the terms of this Agreement or impose any obligations on Allogene, except as approved in writing in advance by Allogene. Each Party shall use Commercially Reasonable Efforts to maintain materially complete, current and accurate records of the activities conducted by or on behalf of such Party under the Research Program and all data and other information resulting from such activities. Such records shall properly reflect all work done and results achieved in good scientific manner and with intention to be appropriate for regulatory and patent purposes.

(f) Notch shall keep accurate records of the Notch FTEs involved in the performance of the Research Program, including time sheets tracking the time such individual spent working in support of the Research Program.

(g) Subject to Section 2.1(a), with respect to each Exclusive Target, Allogene shall have the right to specify whether the Research Plan shall at any particular time be directed to T Cells, NK Cells or both T Cells and NK Cells.

(h) The term of the Research Program shall commence on the Effective Date and expire upon the earlier of (i) the fifth (5<sup>th</sup>) anniversary of the Effective Date, (ii) at Allogene's election, following the JDC's determination that for each Exclusive Target, Notch has met the Success Criteria for all Development Milestones for at least one Product (irrespective of cell type) Directed Against such Exclusive Target, or (iii) the JDC's determination that the Research Program cannot be reasonably pursued against any Exclusive Target due to technical infeasibility or safety issues (the "**Collaboration Term**"). Allogene

shall have the right to terminate the Collaboration Term by written notice if Notch materially fails to perform its obligations under the Research Plan, subject to Sections 2.1(c) and (d), and does not cure such failure within [\*\*\*] days following Notch's receipt of Allogene's written notice of such failure. In such event, at Allogene's request, Notch shall perform the technology transfer described in Section 2.4.

(i) During the Collaboration Term, each Party shall report to the JDC each Calendar Quarter summarizing the results and data obtained from the conduct of the Research Plan. If reasonably necessary for Allogene to perform its work under the Research Plan or to Exploit a Product or exercise its rights under the Agreement, Allogene may request that Notch provide more detailed information and data regarding such results reported by Notch, and Notch shall promptly provide Allogene with such reasonable information and data responsive to such request to the extent in Notch's possession or control, provided that, without limiting Notch's obligations to perform the Research Plan as set forth in this Article 2, Notch shall not be required to perform any additional work in responding to such request beyond transmitting such existing information and data in the form it exists unless Notch and Allogene agree upon reasonable additional funding (including Notch FTEs at the FTE Rate) in accordance with an agreed budget that Allogene will pay to Notch for such additional work.

## 2.2 **Notch Research and Manufacturing Facilities.**

(a) Notch will use Commercially Reasonable Efforts to maintain access to laboratory and process development facilities at [\*\*\*] or similar facility approved by the JDC (the "**Research Facility**") at its own cost. Notch will use Commercially Reasonable Efforts to negotiate a fee-for-service agreement with the Research Facility to maintain access to cGMP manufacturing resources for cGMP master cell line generation and banking to perform the Research Plan as necessary during the Collaboration Term. Such agreement shall not conflict with the terms of this Agreement or impose any obligations upon Allogene, except as expressly approved in advance in writing by Allogene. Allogene shall reimburse Notch in accordance with the Research Budget for its actual, out-of-pocket costs of the Research Facility specifically incurred for the conduct of manufacturing activities pursuant to the Research Plan.

(b) In addition, Allogene shall fully reimburse Notch in accordance with the Research Plan budget for its actual, out-of-pocket costs for Notch's costs of maintaining cGMP facility manufacturing capacity required for Notch's performance under this Agreement (which shall be paid on a pro rata basis if such capacity is also used for other Notch programs). If the Parties enter into a Supply Agreement, then such costs shall be addressed under the Supply Agreement. For clarity, Allogene shall not be responsible for any legal or advisory costs incurred by Notch in contracting for such capacity. Such agreement between Notch and the manufacturer shall not impose any obligations upon Allogene, except as expressly approved in advance in writing by Allogene.

2.3 **Transfer of Know-How and Materials for Research Program.** Each Party shall use Commercially Reasonable Efforts to transfer to the other Party any Materials and Know-How specified in the Research Plan for use by such other Party in conducting the Research Program and performing its obligations under this Agreement in accordance with the timeline for such transfer set forth therein. Each Party shall use the other Party's Materials and Know-How in compliance with Applicable Law and the terms and conditions of this Agreement.

Except as otherwise provided under this Agreement, all Materials and Know-How shall remain the sole property of the providing Party, and shall be returned to such Party or destroyed, in such Party's sole discretion, upon the termination of this Agreement or, solely with respect to Allogene's Materials and Know-How, expiration of the Collaboration Term, whichever is the earlier.

#### 2.4 **Technology Transfer for Collaboration Products.**

(a) For each Collaboration Product, upon the date that is [\*\*\*] days following Notch's completion of its activities under the Research Plan for such Collaboration Product or upon Allogene's written request, the Parties will agree in writing on a plan for the transfer of Notch Know-How relating to such Collaboration Product to Allogene, or its designee, including the manufacturing process therefor (a "**Technology Transfer Plan**"), subject to Section 5.3 and the Supply Agreement, if and when in force. If the Parties do not execute a Supply Agreement pursuant to Section 5.3, Allogene may engage a reputable Third Party manufacturer located in the United States, Europe or Japan and transfer or instruct Notch to transfer the applicable Notch Microbead Technology (including any reagents or other factors necessary to use the Notch Microbead Technology) in accordance with Section 5.3. If the Parties do not execute a Supply Agreement pursuant to Section 5.3, Allogene may not engage a Third Party manufacturer located outside the United States, Europe or Japan without Notch's prior written approval, not to be unreasonably withheld. Prior to any transfer to a Third Party manufacturer, Notch may require that the Third Party manufacturer execute an agreement with Notch, to be negotiated in good faith by Notch, that includes reasonable industry-standard measures to protect Notch Know-How relating to the applicable Collaboration Product and manufacturing process therefor, including reasonable confidentiality and non-use provisions.

(b) The Parties intend that each Technology Transfer Plan encompass the transfer to Allogene of all Notch Know-How (including tangible materials) Controlled by Notch as of the date of such transfer and that is necessary or reasonably useful to enable Allogene's Development and manufacture of such Collaboration Product, excluding any inventory of Notch Microbead cGMP raw materials, work in process and finished Notch Microbeads, which shall be supplied solely to the extent set forth in Section 5.3 or a Supply Agreement. As soon as practical and pursuant to such Technology Transfer Plan, Notch shall commence disclosing and making available to Allogene or its designee the Notch Know-How and materials listed in the Technology Transfer Plan, according to the timeline set forth in the Technology Transfer Plan. Notch shall use Commercially Reasonable Efforts to complete such transfer within such reasonable period as the Parties shall agree in writing in the Technology Transfer Plan. The Parties shall cooperate with each other in good faith to enable a smooth and successful transfer of such Notch Know-How to Allogene. Upon Allogene's reasonable request, Notch shall provide reasonable technical assistance, including making appropriate personnel available to Allogene at reasonable times, places, and frequency, and upon reasonable prior notice, for the purpose of assisting Allogene to understand and use the Notch Know-How in connection with Allogene's Development and manufacture of Collaboration Products, provided that Notch may reasonably condition such provision of assistance on Allogene's funding of any Notch resources needed to respond to such Allogene request (including Notch FTEs at the FTE Rate) in accordance with an agreed budget.



(c) Notch shall, at Allogene's request, use Commercially Reasonable Efforts to make such introductions and facilitate discussions with contract manufacturers, contract research organizations and other Third Parties that have performed services related to each Collaboration Product on behalf of Notch in order for Allogene to evaluate and potentially contract for such Third Parties' services.

## 2.5 Substitution of Initial Targets.

(a) During the Exclusivity Term, Allogene shall have the right to substitute each Initial Target with one (1) substitute Target. To exercise such right, Allogene shall provide Notch with written notice of its intent to substitute an Initial Target with a different Target, which notice shall identify the proposed substitute Target. Notch shall notify Allogene within [\*\*\*] days following its receipt of such notice as to whether such Target is Available or, if such Target is not Available, a brief description of why such Target is not Available (for clarity, Notch shall not be required to disclose the identity of any Third Party that holds a license or option to such Target). If such Target is Available, then it shall become an Exclusive Target (and shall be deemed to be a "**Substitute Target**") and such Initial Target shall cease to be an Exclusive Target and thereafter Allogene shall have no further rights under this Agreement as to such former Exclusive Target. If such Target is not Available, then Allogene shall retain the right to substitute another Target for such Initial Target as set forth above.

(b) Subject to Section 2.1, promptly following the substitution of an Initial Target with a Substitute Target, the JDC shall update the Research Plan to reflect such substitution and the activities to be performed with respect to such Substitute Target, provided that Notch shall not be obligated to undertake such additional work unless and until the Research Budget has also been modified as necessary to cover any expansion to the scope of activities to be required of Notch, which modification may increase the aggregate funding to be paid by Allogene to Notch above [\*\*\*] dollars (US\$[\*\*\*]).

(c) Solely with respect to any Substitute Target that is not a substitute for [\*\*\*], neither Allogene nor any of its Affiliates shall conduct (and shall not facilitate any Third Party to conduct) any clinical development of any Product Directed Against such Substitute Target for an indication that is not a Competitive Indication unless and until Allogene (or any of its Affiliates or Sublicensees) has submitted a BLA for a Product Directed Against such Substitute Target in a Competitive Indication.

## 2.6 Target Option.

(a) Notch hereby grants to Allogene an option to add [\*\*\*] additional Targets as Exclusive Targets under this Agreement, as follows: From the Effective Date through [\*\*\*], Allogene shall have the right, but not the obligation, to propose in writing to Notch from time-to-time additional Targets to be added to this Agreement. Notch shall notify Allogene within [\*\*\*] days following its receipt of such notice as to whether each such Target is Available or, if such Target is not Available, a brief description of why such Target is not Available (for clarity, Notch shall not be required to disclose the identity of any Third Party that holds a license or option to such Target). If such Target is Available, then Allogene shall within [\*\*\*] days following its receipt of Notch's notice of Availability notify Notch whether Allogene is exercising its option with respect to such Target. If Allogene exercises its option with respect

to such Target, then such Target shall become an “**Optioned Target**” and Allogene shall pay to Notch an option exercise fee therefor in accordance with Section 6.2.

(b) Subject to Section 2.1, promptly following Allogene’s exercise of its option with respect to an Optioned Target, the JDC shall update the Research Plan to reflect such substitution and the activities to be performed with respect to such Optioned Target, provided that Notch shall not be obligated to undertake such additional work unless and until the Research Budget has also been modified as necessary to cover any expansion to the scope of activities to be required of Notch, which modification may increase the aggregate funding to be paid by Allogene to Notch above [\*\*\*] dollars (US\$[\*\*\*]).

(c) Neither Allogene nor its Affiliates shall conduct (and shall not facilitate any Third Party to conduct) any clinical development of any Product Directed Against an Optioned Target for an indication that is not a Competitive Indication unless and until Allogene (or any of its Affiliates or Sublicensees) has submitted a BLA for a Product Directed Against such Optioned Target in a Competitive Indication.

**2.7 Right of First Negotiation.** During the Exclusivity Term, Notch hereby grants to Allogene a right of first negotiation with respect to each ROFN Target to acquire an exclusive (even as to Notch and its Affiliates), royalty-bearing, worldwide, sublicenseable license under Notch’s Intellectual Property Rights to Exploit CAR Products Directed Against a ROFN Target (a “ROFN License”), as follows:

(a) During the Exclusivity Term, neither Notch nor its Affiliates shall (i) initiate any IND-enabling GLP toxicity study for any CAR Product Directed Against any ROFN Target (such product, a “**ROFN Product**” and such study and any further studies conducted by Notch or its Affiliates, “**Notch Internal R&D**”), nor (ii) initiate or participate in negotiations for any agreement with a Third Party for a license, an option to acquire a license, or the sale or other transfer under Notch’s Intellectual Property Rights to Exploit any ROFN Product, unless and until the procedures set forth in this Section 2.7 have been fulfilled.

(b) If Notch or any of its Affiliates desires to undertake any activity described in subsection (a)(i) or (a)(ii) above, then Notch shall provide Allogene with written notice thereof, which notice shall specify (i) the ROFN Target, (ii) a summary of the Intellectual Property Rights and data Controlled by Notch and its Affiliates relating to such ROFN Target and ROFN Product(s) and (iii) whether such notice is triggered by subsection (a)(i) or (a)(ii) above (such notice, a “**ROFN Notice**”).

(c) Allogene may exercise its right of first negotiation with respect to such ROFN Target at any time during the [\*\*\*] days following its receipt of such ROFN Notice (the “**Notification Period**”), by providing to Notch a written notice of exercise during such Notification Period. If Allogene exercises such right of first negotiation, then for [\*\*\*] days following Notch’s receipt of Allogene’s notice of exercise (the “**Negotiation Period**”), the Parties shall engage in good faith negotiations regarding the commercially reasonable terms for the ROFN License. During the Negotiation Period, Notch shall provide Allogene with such reasonable additional information regarding such ROFN Target (and any existing ROFN Product(s) Directed Against such ROFN Target Controlled by Notch) and related Intellectual Property Rights as Notch may have in its possession or control and Allogene may reasonably

request, provided that Notch shall not be required to perform any work in responding to such requests beyond transmitting such existing information and data in the form it exists. The Negotiation Period shall be commensurately extended by any period of delay in Notch's transmission of such information.

(d) If Allogene does not exercise its right of first negotiation with respect to a ROFN Target during the applicable Notification Period, or Allogene exercises such right of first negotiation and the Parties do not reach execute an agreement for such ROFN License in accordance herewith prior to the expiration of the applicable Negotiation Period, then, in each such case:

(i) If the ROFN Notice was triggered by subsection (a)(i) above, then Notch and its Affiliates shall thereafter be free to conduct Notch Internal R&D with respect to such ROFN Target, subject to subsection (a)(ii) above; and

(ii) If the ROFN Notice was triggered by subsection (a)(ii) above, then Notch and its Affiliates shall thereafter be free to grant a Third Party a ROFN License with respect to such ROFN Target. Notwithstanding the foregoing, prior to Notch accepting any offer to grant such ROFN License (or any other sale or transfer) to any Third Party on terms that are substantially similar to (or less favorable to Notch than) those last offered by Allogene, Allogene shall have a one-time right of first refusal whereby Notch shall offer such ROFN License (with the same terms and conditions offered by such Third Party) to Allogene in writing, and Allogene shall have [\*\*\*] days following its receipt of Notch's notice to accept such offer in writing, in which case the Parties shall promptly execute a definitive agreement on reasonable and customary terms reflecting such offer and acceptance. Notwithstanding anything to the contrary in this Agreement, Allogene's right of first refusal does not apply where a Third Party has offered Notch terms and conditions for a license to a New Target Product that are substantially better for Notch (considering the entire economic consideration to be received by Notch under such offer) than the terms and conditions last offered by Allogene.

**2.8 Option under Existing Notch Third Party In-License.** If Notch receives a notice from [\*\*\*] pursuant to Section 4.5(a) of the Existing Notch Third Party In-License regarding any Licensor Improvement (as defined in the Existing Notch Third Party In-License) that relates to the Notch Technology, then Notch shall notify Allogene of such Licensor Improvement within [\*\*\*] days of Notch's receipt of such notice. If Allogene wishes to include such Licensor Improvement in its licenses granted under Section 4.2(a) of this Agreement, then (a) Allogene shall so notify Notch within [\*\*\*] days of its receipt of Notch's notice; (b) promptly following its receipt of Allogene's notice, Notch shall notify [\*\*\*] of its interest in exercising its option under Section 4.5(a) of the Existing Notch Third Party In-License with respect to such Licensor Improvement (unless Notch has already provided such notice); and (c) the Parties shall discuss in good faith the terms for such license to such Licensor Improvement. For clarity, this Section 2.8 shall not prevent Notch from exercising such option with respect to any Licensor Improvement that Allogene does not wish to include in its licenses hereunder.

### **3 GOVERNANCE**

3.1 **Alliance Managers.** Each Party shall by written notice to the other Party appoint a principal point of contact to be its project manager (the “**Alliance Manager**”) who shall coordinate and act as a liaison with such other Party with respect to this Agreement and the Research Program and who shall have the authority to act on behalf of their respective Parties. Each Party may from time to time change its Alliance Manager upon written notice and reasonable consultation with the other Party. The Alliance Managers’ responsibilities shall generally include overseeing and supervising its Party’s fulfillment of its obligations under the Research Plan, understanding the obligations of the other Party under the Research Plan, discussing the progress of the Research Program, and identifying barriers to success, key issues and issues-resolution options with the other Party’s Alliance Manager. The Alliance Managers shall not have any authority to amend or interpret this Agreement.

3.2 **Joint Development Committee.** Promptly following the Effective Date, the Parties shall establish a joint development committee to oversee, coordinate and review the activities to be conducted under the Research Plan during the Collaboration Term (the “**Joint Development Committee**” or “**JDC**”). The JDC shall be comprised of at three (3) members from each Party with appropriate relevant expertise (each, a “**Member**”). Each Party may replace any appointed Member at any time upon written notice to the other Party. Each Party shall designate one (1) of its Members as co-chairperson of the JDC. Each of the co-chairpersons shall be responsible, on an alternating basis, with the Allogene co-chairperson having responsibility with respect to the initial meeting, for working with the Alliance Managers to schedule meetings, prepare and circulate an agenda in advance of each meeting. Any JDC member may add topics to the draft agenda. The following shall apply to the JDC and its members:

(a) During the Collaboration Term, the JDC shall meet at least once every Calendar Quarter at times mutually agreed upon by the Parties, or more frequently as the Parties deem appropriate. At least one (1) such meeting per Calendar Year shall be held in person, and all other such meetings may be held by teleconference or videoconference. The location of the meetings to be held in person shall alternate between sites designated by each Party, or as otherwise mutually agreed upon.

(b) The presence of at least one Notch Member and one Allogene Member shall be required to constitute a quorum at any meeting of the JDC.

(c) In addition to its Members, the Parties’ Alliance Managers may attend any meeting of the JDC. Each Party may invite other of its relevant employees or consultants to a JDC meeting as non-voting observers, provided that (i) such Party must provide the other Party with advance written notice identifying each such observer and such other Party has no reasonable objection to such observers, and (ii) such Party shall ensure that such observers are bound by written obligations relating to confidentiality and intellectual property that are consistent with this Agreement.

(d) Each Party shall be responsible for all travel and related costs and expenses for its Members and other representatives to attend meetings of, and otherwise participate on, the JDC.

3.3 **Responsibilities of the JDC.** The responsibilities of the JDC shall include: (a) overseeing, reviewing and coordinating the Parties' implementation of the Research Plan, including reviewing data provided by Notch to evidence its achievement of the Research Milestones and Development Milestones; (b) making key decisions as designated in the Research Plan, including determining whether or not the Research Milestones (as applicable) have been met, as set forth in Section 3.4; (c) subject to Section 2.1, amending the Research Plan, including following the substitution of an Exclusive Target pursuant to Section 2.5 or the addition of an Exclusive Target pursuant to Section 2.6; (d) undertaking and/or approving such other matters as are specifically provided for the JDC under this Agreement; and (e) serving as an initial forum for resolving any disputes between the Parties.

3.4 **Milestone Achievement.** Promptly following Notch's determination that it has achieved a particular Research Milestone or Development Milestone with respect to a Collaboration Product of either Cell Type, Notch shall provide the JDC with a data package that includes the data and information required under the Research Plan and reasonably necessary for the JDC to determine whether the Success Criteria for such milestone has been achieved. The JDC shall have [\*\*\*] days to meet and consider such data package, and to determine in writing whether such Success Criteria have been achieved. The JDC may request that Notch provides additional data and information to assist in such determination, which Notch shall promptly provide. If the JDC determines that the applicable Success Criteria have been achieved, then Allogene shall pay the applicable milestone payment in accordance with Section 6.4 or 6.5, as applicable.

3.5 **Decision-Making.** All of a Party's Members whether present in person or by other means (e.g., teleconference) at any JDC meeting shall vote collectively counting as one vote. Decisions of the JDC shall require the unanimous vote of both Parties. If the JDC is unable to reach a unanimous vote with respect to a particular matter, then the matter shall be escalated for resolution by the CEOs in accordance with Section 13.1. All decisions of the JDC within its authority shall be documented in meeting minutes prepared by Allogene's Alliance Manager. Other communications between or among any members of the JDC outside of a JDC meeting shall not be deemed to constitute a JDC decision unless incorporated in meeting minutes, nor shall any decision of the JDC outside its authority be deemed binding on either Party.

3.6 **Scope of Authority.** The JDC shall have no authority to amend or modify any term or condition of this Agreement, or to determine or waive any compliance therewith.

#### 4. **LICENSES; EXCLUSIVITY**

4.1 **Research Program License.** Subject to the terms and conditions of this Agreement:

(a) Allogene hereby grants to Notch, a non-exclusive, non-sublicenseable (except as set forth in subsection (b) below), non-transferable license during the Collaboration Term (i) to use and practice the Allogene Technology, solely to the extent necessary for Notch to carry out its obligations under the Research Plan, and (ii) to use Allogene's Materials transferred to Notch pursuant to Section 2.3, solely for performing activities under the Research Plan.

(b) The license set forth in subsection (a) shall include the right for Notch to sublicense such rights to its Affiliates, contractors or service providers (but solely to the extent that they are identified in the Research Plan and are performing services solely related to the Research Plan), provided that Notch shall remain fully liable for the acts and omissions of, and for any breach of this Agreement by, such Affiliate(s), contractors and service providers. Except as set forth in this subsection (b), Notch shall not have the right to sublicense to any Third Party without Allogene's consent.

#### 4.2 License to Allogene.

(a) Subject to the terms and conditions of this Agreement, Notch hereby grants to Allogene an exclusive (even as to Notch and its Affiliates, provided that Notch shall retain such rights as are necessary to carry out its obligations under the Research Plan), worldwide, royalty-bearing, sublicenseable (through multiple tiers) license under the Notch Technology to Exploit CAR Products Directed Against one or more Exclusive Targets for use in the Field. Allogene shall remain fully liable for the acts and omissions of, and for any breach of this Agreement by any of its Affiliates or Sublicensees.

(b) Allogene shall not exercise its rights granted under subsection (a) above with respect to the Notch Microbead Technology to make or have made Notch Microbeads, except (i) if the Parties do not enter into a Supply Agreement in accordance with Section 5.3 during the Supply Agreement Negotiation Period, (ii) if the Parties do enter into a Supply Agreement and Allogene terminates the Supply Agreement for Notch's material breach thereof or Notch otherwise fails to fulfill its obligations to supply Notch Microbeads sufficient to support the development and commercialization of the Products in the Field throughout the Territory, or (iii) as otherwise set forth in the Supply Agreement or agreed in writing by the Parties.

#### 4.3 Notch Third Party In-Licenses.

(a) Allogene shall comply, and shall cause its Affiliates and Sublicensees to comply, with all terms and conditions of the Notch Third Party In-Licenses applicable to sublicensees thereunder, provided that such terms and conditions have been provided to Allogene.

(b) Allogene shall be responsible for the payment of all license fees, milestone payments, royalties and other amounts payable under the Notch New Third Party In-Licenses based on Allogene's sublicense rights thereunder, which Allogene shall pay to Notch or directly to the Third Party licensors, as mutually agreed by Notch and Allogene, in time for Notch to satisfy its payment obligations to the applicable Third Party licensors. Notch shall be responsible for the payment of all license fees, milestone payments, royalties and other amounts payable under the Existing Notch Third Party In-License.

(c) Notch shall, and shall cause its Affiliates to:

(i) subject to Allogene's satisfaction of its obligations as a sublicensee thereunder, maintain each Notch Third Party In-License in full force and effect and not terminate such Notch Third Party In-License if the failure to do so would adversely affect, or would

reasonably be expected to adversely affect, Allogene's rights under this Agreement, without Allogene's prior written consent, not to be unreasonably withheld; and

(ii) not amend or waive, or take any action or omit to take any action that would alter, any of Notch's or such Affiliates' rights under any Notch Third Party In-License in any manner that adversely affects, or would reasonably be expected to adversely affect, Allogene's rights under this Agreement without Allogene's prior written consent, not to be unreasonably withheld; and

(iii) Notch shall promptly notify Allogene in writing of the receipt or delivery of any notice of any default under, or any termination or amendment of, any Notch Third Party In-License. If Notch fails to cure any such default and the failure to do so would adversely affect, or would reasonably be expected to adversely affect, Allogene's rights under this Agreement, Allogene shall have the right to cure any such default and subtract any reasonable amounts paid to the counterparty under the applicable Notch Third Party In-License in connection with such cure (other than amounts with respect to Notch New Third Party In-Licenses for which Allogene is responsible as set forth in this Section 4.3) from any amounts due to Notch hereunder.

(d) At Allogene's request, Notch shall use reasonable efforts to obtain the written agreement of the counterparty to any Notch Third Party In-License that, in the event of any termination of such Notch Third Party In-License, which termination does not result from any failure by Allogene or its Affiliates or Sublicensee to comply with the applicable terms of this Agreement or of such Notch Third Party In-License, such counterparty shall grant to Allogene a direct license under the Intellectual Property Rights covered by such Notch Third Party In-License that are equivalent in scope to the sublicense under such Intellectual Property Rights granted to Allogene hereunder, under the same terms as are in such Notch Third Party In-License (adjusted for any differences in the scope of such direct license from the license granted to Notch under such Notch Third Party In-License), and provided that such counterparty shall not be required to accept any obligations greater than those provided for in such Notch Third Party In-License.

**4.4 No Other Rights.** Except for the rights expressly granted under this Agreement, no right, title, or interest of any nature whatsoever is granted whether by implication, estoppel, reliance, or otherwise, by either Party to the other Party. All rights that are not specifically granted herein are reserved to the possessing Party.

**4.5 Exclusivity.**

(a) During the Exclusivity Term, neither Notch nor any of its Affiliates shall sell, license or otherwise transfer any Notch Technology to any Third Party for application to products in the Field the primary mechanism of action of which is modulation of any Exclusive Target.

(b) During the Exclusivity Term and other than as set forth in the Research Plan, neither Notch nor any of its Affiliates shall, itself or with any Third Party, research, develop, manufacture or otherwise progress [\*\*\*].

(c) During the Exclusivity Term and other than as set forth in the Research Plan, neither Notch nor any of its Affiliates shall, itself or with any Third Party, research, develop, manufacture or otherwise progress [\*\*\*] (such products, together with any products described in subsection (b) above, “**Competing Products**”).

(d) “**Exclusivity Term**” means the period commencing on the Effective Date and expiring on [\*\*\*]. Notwithstanding the foregoing, for each Exclusive Target for which Allogene is conducting (itself or through an Affiliate or Sublicensee) development or commercialization of a Product Directed Against such Exclusive Target at the end of the period set forth in the immediately preceding sentence, the Exclusivity Term with respect to such Exclusive Target shall be extended until the earliest of [\*\*\*].

4.6 **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Notch to Allogene, are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Bankruptcy Code, licenses of rights to “intellectual property” as defined under Article 101(35A) of the Bankruptcy Code. The Parties agree that Allogene, as a licensee of such Intellectual Property Rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the Bankruptcy Code. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against Notch under the Bankruptcy Code or analogous provisions of applicable Laws outside the United States, Allogene will be entitled to a complete duplicate of (or complete access to, as appropriate) any intellectual property licensed to Allogene and all embodiments of such intellectual property, which, if not already in Allogene’s possession, will be promptly delivered to it (a) upon any such commencement of a bankruptcy proceeding upon Allogene’s written request therefor, unless Notch elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement in the bankruptcy proceeding, upon written request therefor by Allogene. The Parties further agree that, upon the occurrence of a bankruptcy event, each Party shall have the right to retain and enforce their rights under this Agreement.

## 5. **DEVELOPMENT; COMMERCIALIZATION**

5.1 **Generally.** Following the completion of the technology transfer described in Section 2.4 with respect to a Collaboration Product, Allogene shall have sole responsibility for the development and commercialization of such Collaboration Product. In any event, following the Collaboration Term and for the remainder of the Term, as between the Parties, Allogene shall have sole responsibility for the development and commercialization of Products. Following the Collaboration Term, Allogene shall use Commercially Reasonable Efforts to develop and commercialize at least one (1) Product for each of (a) the treatment at least one B-Cell Malignancy and (b) the treatment of Multiple Myeloma, in each case ((a) and (b)) in the United States and in the European Union. The timelines for Allogene’s development and commercialization of the two Products set forth in the foregoing clauses (a) and (b) may vary based on the factors set forth in the definition of Commercially Reasonable Efforts relating to such Products (e.g., in some circumstances, one of such Products may progress further in development at an earlier point in time based on such factors).

5.2 **Reports.** On an Exclusive Target-by-Exclusive Target basis, following the disbanding of the JDC, and until the First Commercial Sale of the first Product Directed Against such Exclusive Target, Allogene shall provide Notch with a written report providing a status of Allogene’s development (including registration) of Products Directed Against such Exclusive



Target annually. Such report shall cover the previous twelve (12) month period and shall be provided by Allogene no later than [\*\*\*] days after each Calendar Year. Each such update shall summarize Allogene's (either by itself or through its Affiliates and its Sublicensees) activities with respect to Exploitation of such Products.

5.3 **Supply of Notch Microbeads.** For [\*\*\*] days following Allogene's request therefor, the Parties shall seek in good faith to negotiate the commercially reasonable terms of supply agreement pursuant to which Notch would supply to Allogene, its Affiliates and its Sublicensees the Notch Microbeads sufficient to support the development and commercialization of the Products in the Field throughout the Territory (a "**Supply Agreement**"), provided that Notch shall not be obligated to negotiate a Supply Agreement after [\*\*\*] months after the Effective Date. If the Parties do not enter into a Supply Agreement within such [\*\*\*] day period and prior to [\*\*\*] months after the Effective Date (or such longer period as the Parties may agree in writing) (the "**Supply Agreement Negotiation Period**"), then Notch shall transfer to Allogene or its designee applicable Notch Microbead Technology (including any reagents or other factors necessary to use the Notch Microbead Technology) in accordance with Section 2.4, subject to Allogene reimbursing Notch for the cost of any tangible materials included in such transfer that were not acquired or generated using Research Budget funding previously paid by Allogene. If the Parties execute a Supply Agreement that relates to the supply of Notch Microbeads for a particular Product and Allogene thereafter requires Notch Microbeads to be supplied for an additional Product, then the Parties shall follow the procedures set forth in this Section 5.3 to amend the existing Supply Agreement for the supply of Notch Microbeads for any additional Product. For clarity, to the extent the Parties were previously unable to negotiate a Supply Agreement or amendment thereto as set forth above, Allogene shall have the right to request Notch to transfer to its designee the Notch Microbead Technology (including any reagents or other factors necessary to use the Notch Microbead Technology) in accordance with Section 2.4 for Product, subject to Allogene reimbursing Notch for the cost of any tangible materials included in such transfer that were not acquired or generated using Research Budget funding previously paid by Allogene.

## 6. PAYMENTS

### 6.1. Initial Consideration; Option Exercise Fee.

(a) In consideration for the rights granted to Allogene under this Agreement, Allogene shall pay to Notch a one-time-only, non-refundable, non-creditable payment of ten million Dollars (\$10,000,000) on the Effective Date.

(b) On the Effective Date, Allogene shall purchase [\*\*\*] shares of Notch's Series Seed convertible preferred stock at \$[\*\*\*] per share, pursuant to the stock purchase agreement and related agreements entered or to be entered into between the Parties of even date herewith.

6.2. **Option Exercise Fee.** For each Optioned Target, Allogene shall pay to Notch an option exercise fee of [\*\*\*] Dollars (\$[\*\*\*]) within [\*\*\*] days following its receipt of Notch's invoice therefor, which invoice shall not be sent until Allogene has exercised its option with respect to such Target in accordance with Section 2.6.

### 6.3. Payment of Research Costs.

(a) Advance Payment. Within [\*\*\*] days of the Effective Date, Allogene shall pay to Notch an amount equal to Notch's estimated Research Costs to be incurred under the Research Plan in accordance with the Research Budget (as set forth in the initial Research Plan) for the then-current Calendar Quarter. Thereafter, for each Calendar Quarter in which Notch is anticipated to activities under the Research Plan, Notch shall submit to Allogene an invoice setting forth Notch's estimated Research Costs to be incurred based on the then-current Research Budget for such Calendar Quarter, no later than [\*\*\*] Business Days following the first day of such Calendar Quarter (the "**Advance Invoice**").

(b) True-Up. Within [\*\*\*] days after the end of each Calendar Quarter in which Notch has conducted activities under the Research Plan, Notch shall submit to Allogene a reasonably detailed reconciliation report setting forth the actual Research Costs incurred by or on account of Notch to conduct such activities in such Calendar Quarter and any credits or deficits from the corresponding Research Advance Invoice previously provided for such Calendar Quarter (the "**True-Up Report**"). If the estimated Research Costs paid by Allogene pursuant to subsection (a) above for such prior calendar quarter are less than Notch's actual Research Costs for such quarter, then Allogene shall pay the deficit to Notch as described in this subsection (b) to the extent such amounts do not exceed the corresponding amounts in then-current Research Budget (exclusive of Research Costs incurred in accordance with Section 2.2). If the estimated Research Costs paid by Allogene pursuant to subsection (a) above for such prior Calendar Quarter are more than Notch's actual Research Costs for such Calendar Quarter, then the excess shall be credited toward the Advance Invoice for the current Calendar Quarter (except where such invoice is the final such invoice to be provided by Notch, in which case the excess shall be refunded by Notch to Allogene within [\*\*\*] days after the delivery of such invoice).

(c) Timing of Payments. For ease of administration, Allogene shall pay Notch a single payment reflecting the amount due under the Advance Invoice for the current Calendar Quarter plus any deficits (or less any credits) reflected in the True-Up Report for the prior Calendar Quarter within the later of (i) [\*\*\*] days of Allogene's receipt of such Advance Invoice, or (ii) [\*\*\*] days of Allogene's receipt of such True-Up Report. Notch shall provide Allogene with sufficient detail and supporting documentation of the costs for which payments are sought hereunder, and the periods for payment set forth above shall be commensurately extended for any delay in the provision thereof or for the resolution of any good faith dispute relating thereto. In no event shall Allogene be obligated to reimburse Notch for any amounts in excess of the corresponding funding amounts set forth in the applicable Research Budget, unless otherwise agreed in writing by an authorized representative of Allogene.

6.4. **Research Milestones**. In consideration for the rights granted to Allogene under this Agreement, Allogene shall make the following non-refundable, non-creditable milestone payments to Notch within [\*\*\*] days from Allogene's receipt of Notch's invoice after Notch's achievement of the Success Criteria for the applicable milestone:

<b>Research Milestone</b>		<b>Milestone Amount Due</b>
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

Each of the milestone payments set forth in the table above shall be payable only once, the first time the Success Criteria for the applicable Research Milestone is achieved by Notch and irrespective of the number of Exclusive Targets with respect to which such Research Milestone is achieved. The aggregate amount payable by Allogene for all Research Milestones shall not

exceed seven million two hundred fifty thousand Dollars (\$7,250,000). The determination of the achievement of each Research Milestone shall be made pursuant to Section 3.4.

6.5. **Development Milestones.** In consideration for the rights granted to Allogene under this Agreement, Allogene shall make the following non-refundable, non-creditable milestone payments to Notch within [\*\*\*] days from Allogene’s receipt of Notch’s invoice after Notch’s achievement of the Success Criteria for the applicable milestone:

<u>Development Milestone</u>			<u>Milestone Amount Due</u>
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Each of the milestone payments set forth in the table above shall be payable only once per Exclusive Target, the first time the Success Criteria for the applicable Development Milestone for such Exclusive Target is achieved by Notch, and irrespective of the number of times a Development Milestone is achieved with respect to an Exclusive Target. If any Development Milestone is achieved for an Initial Target which is subsequently replaced by a Substitute Target, then such achieved Development Milestone shall not be paid for such Substitute Target; however, Allogene shall pay for any Development Milestones achieved by Notch for such Substitute Target that were not paid for such Initial Target. The aggregate amount payable by Allogene for all Development Milestones achieved by Notch with respect to an Exclusive Target (including an Initial Target and its Substitute Target, collectively) shall not exceed four million Dollars (\$4,000,000). The determination of the achievement of any Development Milestone shall be made pursuant to Section 3.4.

Notwithstanding the foregoing, Allogene shall only be required to pay one set of Development Milestones relating to any Bi-Specific Product that meets a Development Milestone and that is Directed Against two (2) or more Exclusive Targets (each a “**Bi-Specific Excluded Target**”); provided that Allogene shall thereafter pay any additional Development Milestones that are achieved for any further Product that is Directed Against a Bi-Specific Excluded Target, subject to the limitations that each milestone payment be payable only once per Exclusive Target and that the aggregate amount payable by Allogene for all Development Milestones achieved by Notch with respect to an Exclusive Target (including an Initial Target and its Substitute Target, collectively) shall not exceed four million Dollars (\$4,000,000). For example, if a Development Milestone is first achieved by a Product Directed Against an Exclusive Target and then such Development Milestone is achieved by a Bi-Specific Product Directed Against such Exclusive Target and a second Exclusive Target as to which no Product has previously achieved such Development Milestone, the applicable milestone payment shall become payable based on such achievement by such Bi-Specific Product.

6.6. **Clinical and Regulatory Milestones.** In consideration for the rights granted to Allogene under this Agreement, Allogene shall make the following non-refundable, non-creditable milestone payments to Notch following the achievement of the following milestones by Allogene or any of its Affiliates or Sublicensees:

<u>Milestone</u>		<u>Milestone Amount Due for First T Cell Product</u>	<u>Milestone Amount Due for First NK Cell Product</u>
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Each of the milestone payments set forth in the table above shall be payable only once per Exclusive Target per Cell Type, the first time such milestone for such Exclusive Target and Cell Type is achieved, and irrespective of the number of times such milestone is achieved with respect to an Exclusive Target and Cell Type. If any milestone above is achieved for an Initial Target which is subsequently replaced by a Substitute Target, then such achieved milestone shall not be paid for such Substitute Target; however, Allogene shall pay for any milestones above achieved by Allogene or any of its Affiliates or Sublicensees for such Substitute Target that were not paid for such Initial Target. The aggregate amount payable by Allogene under this Section 6.6 for all milestones achieved by Allogene, its Affiliates and its Sublicensees with respect to an Exclusive Target (including an Initial Target and its Substitute Target, collectively) shall not exceed [\*\*\*] Dollars (\$[\*\*\*]) per Cell Type. Allogene shall notify Notch within [\*\*\*] days following the achievement of any milestone above (or, if achieved by a Sublicensee, within [\*\*\*] days following its receipt of notice of such achievement) and shall pay the corresponding milestone payment within [\*\*\*] days following its receipt of Notch's invoice therefor.

Notwithstanding the foregoing, Allogene shall only be required to pay one set of clinical and regulatory milestones relating to any Bi-Specific Product that meets a clinical or regulatory milestone and that is Directed Against two (2) or more Bi-Specific Excluded Targets; provided that Allogene shall thereafter pay any additional clinical and regulatory milestones that are achieved for any further Product that is Directed Against a Bi-Specific Excluded Target, subject to the limitations that each milestone payment be payable only once per Exclusive Target and that the aggregate amount payable by Allogene for all clinical and regulatory milestones achieved by Allogene, its Affiliates and its Sublicensees with respect to an Exclusive Target (including an Initial Target and its Substitute Target, collectively) shall not exceed [\*\*\*] Dollars (\$[\*\*\*]) per Cell Type. For example, if a clinical or regulatory milestone is first achieved by a Product Directed Against an Exclusive Target and then such clinical or regulatory milestone is achieved by a Bi-Specific Product Directed Against such Exclusive Target and a second Exclusive Target as to which no Product has previously achieved such clinical or regulatory milestone, the applicable milestone payment shall become payable based on such achievement by such Bi-Specific Product.

6.7. **Commercial Milestones.** In consideration for the rights granted to Allogene under this Agreement, Allogene shall make the following non-refundable, non-creditable milestone payments to Notch following the achievement of the following milestones based on cumulative annual, worldwide Net Sales by Allogene or any of its Affiliates or Sublicensees:

<u>Milestone</u>		<u>Milestone Amount Due for First T Cell Product</u>	<u>Milestone Amount Due for First NK Cell Product</u>
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

Each of the milestone payments set forth in the table above shall be payable only once per Exclusive Target per Cell Type, the first time such milestone for such Exclusive Target and Cell Type is achieved, and irrespective of the number of times such milestone is achieved with respect to an Exclusive Target and Cell Type. If any milestone above is achieved for an Initial Target which is subsequently replaced by a Substitute Target, then such achieved milestone shall not be paid for such Substitute Target; however, Allogene shall pay for any milestones above achieved by Allogene or any of its Affiliates or Sublicensees for such Substitute Target that were not paid for such Initial Target. The aggregate amount payable by Allogene under this Section 6.7 for all milestones achieved by Allogene, its Affiliates and its Sublicensees with respect to an Exclusive Target (including an Initial Target and its Substitute Target, collectively) shall not exceed [\*\*\*] Dollars (\$[\*\*\*]) per Cell Type. Allogene shall notify Notch contemporaneously with its provision of its royalty report under Section 6.11 for the Calendar Quarter in which such milestone was achieved and shall pay the corresponding milestone payment within [\*\*\*] days following its receipt of Notch's invoice therefor.

Notwithstanding the foregoing, Allogene shall only be required to pay one set of commercial milestones relating to any Bi-Specific Product that meets a commercial milestone and that is Directed Against two (2) or more Bi-Specific Excluded Targets; provided that Allogene shall thereafter pay any additional commercial milestones that are achieved for any further Product that is Directed Against a Bi-Specific Excluded Target, subject to the limitations that each milestone payment be payable only once per Exclusive Target and that the aggregate amount payable by Allogene for all commercial milestones achieved by Allogene, its Affiliates and its Sublicensees with respect to an Exclusive Target (including an Initial Target and its Substitute Target, collectively) shall not exceed [\*\*\*] Dollars (\$[\*\*\*]) per Cell Type. For example, if a commercial milestone is first achieved by a Product Directed Against an Exclusive Target and then such commercial milestone is achieved by a Bi-Specific Product Directed Against such Exclusive Target and a second Exclusive Target as to which no Product has previously achieved such commercial milestone, the applicable milestone payment shall become payable based on such achievement by such Bi-Specific Product.

6.8. **Royalties.** Subject to Sections 6.9 and 6.10, following Regulatory Approval, on a an Exclusive Target-by-Exclusive Target basis and Cell Type-by-Cell Type basis, Allogene shall pay to Notch non-creditable, non-refundable royalties on aggregate annual Net Sales of all Products Directed Against such Exclusive Target in the Territory, as calculated by multiplying

the applicable royalty rate by the corresponding amount of incremental Net Sales of all such Products in the Territory in each Calendar Year as follows, provided that, in the case of Bi-Specific Products, such Products shall be deemed to be Directed Against one (but not both) of the applicable Exclusive Targets for such Bi-Specific Product (i.e., royalties for such Product shall be calculated as though the entire Product were of a single Cell Type). Notwithstanding the foregoing, if (a) there are Net Sales of Products Directed Against one of the Exclusive Targets a Bi-Specific Product is Directed Against, such Bi-Specific Product Net Sales shall be aggregated with such Products, and (b) there are Net Sales of Products Directed Against one of the Exclusive Targets of a Bi-Specific Product and Net Sales of Products Directed Against the second Exclusive Target of a Bi-Specific Product, the Net Sales of the Bi-Specific Product shall be allocated equally between the Exclusive Targets.

<u>Annual Net Sales</u>	<u>Royalty Rate for T Cell Products</u>	<u>Royalty Rate for NK Cell Products</u>
For that portion of annual aggregate Net Sales of all Products of such Cell Type Directed Against a particular Exclusive Target in a Calendar Year that are less than or equal to [***] Dollars (\$[***])	[***]%	[***]%
For that portion of annual aggregate Net Sales of all Products of such Cell Type Directed Against a particular Exclusive Target in a Calendar Year that are greater than [***] Dollars (\$[***]) and less than or equal to [***] Dollars (\$[***])	[***]%	[***]%
For that portion of annual aggregate Net Sales of all Products of such Cell Type Directed Against a particular Exclusive Target in a Calendar Year that are greater than [***] Dollars (\$[***]) and less than or equal to [***] Dollars (\$[***])	[***]%	[***]%
For that portion of annual aggregate Net Sales of all Products of such Cell Type Directed Against a particular Exclusive Target in a Calendar Year that are greater than [***] Dollars (\$[***]) and less than or equal to [***] Dollars (\$[***])	[***]%	[***]%
For that portion of annual aggregate Net Sales of all Products of such Cell Type Directed Against a particular Exclusive Target in a Calendar Year that are greater than [***] Dollars (\$[***])	[***]%	[***]%

#### 6.9. Royalty Floors and Offsets.

(a) If, on a country-by-country and Product-by-Product basis, there is no Valid Claim in such country that Covers the manufacture, use or sale of such Product in such country and, solely with respect to countries outside of the United States, there is no applicable Regulatory Exclusivity that covers the Product in such country at the time of sale, then the applicable royalty rate under Section 6.8 shall be reduced by [\*\*\*] percent ([\*\*\*]%), subject to Section 6.9(c).

(b) If it is Necessary or Useful for Allogene to license one or more Patent Rights from one or more Third Parties in order to Exploit any Product, whether directly or through any Allogene Affiliate or Sublicensee, then Allogene may, in its sole discretion, negotiate and obtain a license under such Patent Right(s) (each such Third Party license, or any such Third Party, referred to herein as a “**Third Party License**”). Any royalty otherwise payable to Notch under this Agreement with respect to Net Sales of any Product by Allogene, its Affiliates or Sublicensees will be reduced by [\*\*\*] percent ([\*\*\*]%) of the amounts paid to Third Parties pursuant to any Third Party Licenses, provided that in no event will the total royalty payable to Notch be less than [\*\*\*] percent ([\*\*\*]%) of the royalty amounts otherwise payable to Notch and provided that if any portion of any such reduction is limited by the immediately preceding proviso, the portion that is not permitted to be deducted may be carried forward for reduction in subsequent Calendar Quarters, subject to the limitation in the immediately preceding proviso, until such amounts have been expended. For purposes of this Section 6.9(b), (i) “**Necessary**” means that, without a license to use the Third Party’s Patent Right, the Exploitation of any Product in the form such Product exists at the time that the Third Party License is executed would, in Allogene’s reasonable opinion, based on written advice from counsel, infringe such Third Party’s Patent Right, and (ii) “**Useful**” means that Allogene has determined in its discretion that use of such Third Party’s Patent Right would enhance the commercial potential of any Product. For clarity, a Third Party License may include a license for Patent Rights and Know-How and all payments thereunder shall be subject to the offset set forth in this Section 6.9.

(c) Notwithstanding subsection (a) above, in no event shall the royalty rate on the sale of any Product in any country be reduced below [\*\*\*] percent ([\*\*\*]%).

6.10. **Royalty Term.** Royalties shall be paid under Section 7.6, on a country-by-country and Product-by-Product basis, commencing on First Commercial Sale of such Product in such country and continuing until the latest of (a) the date upon which there is no Valid Claim of the Notch Patents (including Joint Patents) in such country of sale, (b) the expiration of applicable data or other regulatory exclusivity in such country of sale or (c) the tenth (10<sup>th</sup>) anniversary of the First Commercial Sale of such Product in such country (collectively, the “**Royalty Term**”). Following the Royalty Term, Allogene’s license rights under any Notch Technology with respect to such Product and country shall be perpetual, irrevocable, fully paid up and royalty-free.

6.11. **Royalty Reports and Payment.** Within [\*\*\*] days after the end of each Calendar Quarter, commencing with the Calendar Quarter during which the First Commercial Sale of the first Product is made anywhere in the Territory, Allogene shall provide Notch with a report that contains the following information for the applicable calendar quarter, on a Product-by-Product and country-by-country basis: (a) the gross sales and Net Sales of each Product, (b) a summary of the deductions from gross sales applied in calculating Net Sales, (c) the basis for any adjustments to the royalty payable for the sale of such Product and (d) the royalty due hereunder for the sale of such Product. Concurrent with the delivery of the foregoing applicable quarterly report, Allogene shall pay in Dollars all royalties due to Notch with respect to Net Sales by Allogene and its Affiliates and Sublicensees for such Calendar Quarter.



6.12. **Currency; Exchange Rate.** All payments to be made by Allogene to Notch under this Agreement shall be made in Dollars by bank wire transfer in immediately available funds to a bank account designated by written notice from Notch. The rate of exchange to be used in computing the amount of currency equivalent in Dollars shall be made at the average of the closing exchange rates reported on the Oanda website (<http://www.oanda.com/currency/historical-rates/> ) with Interbank +/- 0%, or such other source as the Parties may agree in writing, for the first, middle and last business days of the applicable reporting period for the payment due.

6.13. **Taxes.**

(a) **Withholding.** If any Applicable Law requires Allogene to withhold taxes with respect to any payment to be made by Allogene pursuant to this Agreement, Allogene will notify Notch of such withholding requirement prior to making the payment to Notch and provide such reasonable assistance to Notch, including the provision of such standard documentation as may be required by a tax authority, as may be reasonably necessary in Notch's efforts to claim an exemption from or reduction of such taxes. At Notch's request, Allogene shall delay making any payment otherwise due hereunder in order to provide time for Notch to provide to Allogene documentation necessary to claim an exemption from or reduction of such taxes prior to withholding; for clarity, no interest shall apply during such period and Allogene shall not be required to pay any such payment to Notch on less than [\*\*\*] days' notice from Notch following such delay request that such payment is to be paid. Allogene will, in accordance with such Applicable Law withhold taxes from the amount due, remit such taxes to the appropriate tax authority, and furnish Notch with proof of payment of such taxes within [\*\*\*] days following the payment. If taxes are paid to a tax authority, Allogene shall provide reasonable assistance to Notch to obtain a refund of taxes withheld, or obtain a credit with respect to taxes paid.

(b) **VAT.** All payments due to Notch from Allogene pursuant to this Agreement shall be paid exclusive of any value-added tax ("**VAT**") (which, if applicable, shall be payable by Allogene upon receipt of a valid VAT invoice). If Notch determines that it is required to report any such tax, Allogene shall promptly provide Notch with applicable receipts and other documentation necessary or appropriate for such report. For clarity, this Section is not intended to limit Allogene's right to deduct value-added taxes in determining Net Sales.

6.14. **Interest.** Any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement will bear interest at a rate equal to the lesser of: [\*\*\*], in each case calculated on the number of days such payment is delinquent.

## 7. **TECHNOLOGY OWNERSHIP**

7.1 **Background Technology.** As between the Parties, each Party will own and retain all right, title and interest in its Background Technology.

7.2 **Ownership of Inventions.** Ownership of all Inventions shall be assigned based on inventorship, as determined in accordance with the rules of inventorship under United States patent laws. All jointly owned Inventions shall be referred to as "**Joint Technology**" and each Party shall own an undivided half interest in the Joint Technology and any Patent Rights claiming such Joint Technology ("**Joint Patents**"). Subject to the licenses granted to the other

Party under this Agreement, and Section 8.5(c) with respect to enforcement of such Joint Technology, neither Party will have any obligation to obtain any approval or consent of, nor pay a share of the proceeds to or account to, the other Party to practice, enforce, license, assign or otherwise exploit Inventions or intellectual property included within Joint Technology, and each Party hereby waives any right it may have under the laws of any jurisdiction to require such approval, consent or accounting. Each Party agrees to execute all papers and otherwise agrees to assist the other Party as reasonably required, to perfect in the other Party the rights, title and other interests owned by such Party under this Section and Intellectual Property Rights relating thereto, as applicable.

7.3 **Disclosure of Research Program Inventions.** Each Party shall promptly disclose to the other Party, in writing, no later than the occurrence of the first JDC meeting following such conception, all Research Program Inventions, including all invention disclosures or other similar documents submitted to such Party by its, or its Affiliates', employees, agents or contractors relating to such Research Program Inventions, and shall respond promptly to reasonable requests from the other Party for additional information relating to such Research Program Inventions.

## 8. PATENT PROSECUTION AND ENFORCEMENT

### 8.1 Notch Patent(s).

(a) As between the Parties, and subject to subsection (b) below, Notch will be solely responsible, at its own cost, for the Prosecution and Maintenance of all Notch Patents, excluding all Joint Patents. With respect to any Notch Patents, Notch shall consult with Allogene and keep Allogene reasonably informed of the status of such Notch Patents and shall promptly provide Allogene with material correspondences received from any patent authorities in connection therewith. In addition, Notch shall promptly provide Allogene with drafts of all proposed material filings and correspondences to any patent authorities with respect to the Notch Patents for Allogene's review and comment prior to the submission of such proposed filings and correspondences. Notch shall confer with Allogene and shall give good faith consideration to Allogene's comments in relation to such Prosecution and Maintenance, and shall use reasonable efforts to implement any reasonable changes requested by Allogene towards the objective of optimizing overall patent protection with respect to the Notch Patents. Allogene shall provide any such comments within [\*\*\*] days of receiving the draft filings and correspondences from Notch. If Allogene does not provide comments within such period of time, then Allogene shall be deemed to have no comment to such proposed filings or correspondences.

(b) Subject to the terms of any applicable Notch Third Party In-License (provided that such terms have been provided to Allogene), if Notch wishes to abandon or cease Prosecution and Maintenance of any Notch Patent, Notch shall provide reasonable prior written notice to Allogene of such intention to abandon (which notice shall, to the extent possible, be given no later than [\*\*\*] days prior to the next deadline for any action that must be taken with respect to any such Notch Patent in the relevant patent office). In such case, upon Allogene's written election, Allogene shall have the right, but not the obligation, to assume Prosecution and Maintenance of such Notch Patent at Allogene's expense. If Allogene elects to assume the Prosecution and Maintenance of such Notch Patent, then Notch shall promptly

transfer to Allogene's patent counsel all relevant files and materials and Allogene shall have the right to deduct [\*\*\*] percent ([\*\*\*]%) of the reasonable costs of Prosecution and Maintenance against milestone payment and royalty amounts payable to Notch hereunder.

8.2 **Allogene Patents.** As between the Parties, Allogene will be solely responsible, at its own cost, and at its discretion, for preparing, filing, prosecuting (including, but not limited to provisional, reissue, continuing, continuation-in-part, and substitute applications and any foreign counterparts thereof), and maintaining all Patent Rights included within Allogene Background Technology and any Patent Rights Controlled by Allogene, excluding Joint Patents (collectively, the "**Allogene Patents**").

8.3 **Joint Patents.**

(a) Subject to subsection (b) below, Allogene shall be solely responsible, at Allogene's cost, and at its discretion, for the Prosecution and Maintenance of the Joint Patents. Allogene shall consult with Notch and keep Notch reasonably informed of the status of the Joint Patents and shall promptly provide Notch with material correspondences received from any patent authorities in connection therewith. In addition, Allogene shall promptly provide Notch with drafts of all proposed material filings and correspondences to any patent authorities with respect to the Allogene Prosecuted Patents for Notch's review and comment prior to the submission of such proposed filings and correspondences. Allogene shall confer with Notch and shall take into consideration Notch's comments in relation to such Prosecution and Maintenance, and shall use reasonable efforts to implement any reasonable changes requested by Notch towards the objective of optimizing overall patent protection for such Joint Patents prior to submitting such filings and correspondences, provided that Notch shall provide such comments within [\*\*\*] days of receiving the draft filings and correspondences from Allogene. If Notch does not provide comments within such period of time, then Allogene may proceed without obtaining or considering such comments in order to continue the Prosecution and Maintenance of the Joint Patents on a timely basis in Allogene's reasonable discretion. In case of disagreement between the Parties with respect to the Prosecution and Maintenance of the Joint Patents, the final decision shall be made by Allogene with the objective of optimizing overall patent protection for such Joint Patents.

(b) If Allogene wishes to abandon or cease Prosecution and Maintenance of any Joint Patent, Allogene shall provide reasonable prior written notice to Notch of such intention to abandon (which notice shall, to the extent possible, be given no later than [\*\*\*] days prior to the next deadline for any action that must be taken with respect to any such Joint Patent in the relevant patent office). In such case, upon Notch's written election, Notch shall have the right, but not the obligation, to assume Prosecution and Maintenance of such Joint Patent at Notch's expense. If Notch elects to assume the Prosecution and Maintenance of such Joint Patent, then Allogene shall promptly transfer to Notch's patent counsel all relevant files and materials and Notch shall keep Allogene reasonably informed regarding the Prosecution and Maintenance.

8.4 **Collaboration.** Each Party shall provide the other Party all reasonable assistance and cooperation in the Prosecution and Maintenance efforts under this Article 8, including providing any necessary powers of attorney and executing any other required documents or

instruments for such prosecution. The Party assuming such Prosecution and Maintenance responsibilities shall have the right to engage its own counsel to perform such activities.

## 8.5 Enforcement

(a) The Parties hereto shall inform each other promptly in writing of any alleged or threatened Infringement by any Third Party of any Patent Right included within the Notch Patents, Joint Patents or any Allogene Patents, where such infringement adversely affects or is expected to adversely affect any Product in the Field, including any “patent certification” filed in the United States under 21 U.S.C. §355(b)(2) or 21 U.S.C. §355(j)(2) or similar provisions in other jurisdictions and of any declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any of the Notch Patents, Joint Patents, or any Allogene Patents (collectively “**Product Infringement**”). The Parties shall consult with each other regarding any actions to be taken with respect to such Product Infringement, including sharing all information available to such Party regarding such alleged Product Infringement.

(b) Allogene shall have the exclusive right to bring and control any legal action in connection with any Product Infringement in the Territory that relates to any Allogene Patent, at its own expense as it reasonably determines appropriate.

(c) Subject to the terms of any applicable Notch Third Party In-License and provided that such terms have been provided to Allogene, for Product Infringement in connection with a Notch Patent or Joint Patent, Allogene shall have the first right to bring and control any legal action in connection with such Product Infringement at its own cost and expense, and Notch shall have the right to be represented in any action by counsel of its choice. Allogene shall have a period of [\*\*\*] days after its receipt or delivery of notice under subsection (a) to elect to so enforce the applicable Notch Patents or Joint Patents in the Field in the Territory (or to settle or otherwise secure the abatement of such Product Infringement). If Allogene fails to commence a suit to enforce the applicable Notch Patents or Joint Patents, or to settle or otherwise secure the abatement of such Product Infringement within such period, then Notch shall have the right, but not the obligation, to commence a suit or take action to enforce such Notch Patents or Joint Patents, as applicable, in the Field in the Territory at its own cost and expense. In such event, promptly after the expiration of the applicable [\*\*\*]-day period, or Allogene’s notice to Notch that it does not elect to enforce such Notch Patents or Joint Patents, the Parties shall meet to discuss in good faith the strategy for enforcing such Patent Rights. Notch shall reasonably consider Allogene’s views with respect to such enforcement.

(d) The Party enforcing a Patent Right under subsection (b) or (c) above shall keep the other Party reasonably informed as to the status of, and all material developments in, such action, and reasonably consider and incorporate such other Party’s input regarding the strategy and handling of such enforcement activities. Such other Party shall provide the enforcing Party reasonable assistance in such enforcement, at the enforcing Party’s request and expense, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required or if reasonably beneficial for the action. Such other Party shall have the right to be represented in any such action by counsel of its choice, at its expense. In connection with any such proceeding, the Party bringing the action shall not enter into any settlement admitting the invalidity of, or otherwise impairing the other Party’s

rights in, the Patent Rights that are the subject of the applicable enforcement action without the prior written consent of the other Party.

(e) Notch shall have the exclusive right to enforce the Notch Patents, other than Joint Patents, for any Infringement that is not a Product Infringement at its own expense as it reasonably determines appropriate. Allogene shall have the exclusive right to enforce the Allogene Patents for any Infringement, other than a Product Infringement, at its own expense as it reasonably determines appropriate. With respect to any Infringement, other than a Product Infringement, relating to any Joint Patents, each Party shall have the right to enforce such Joint Patents as its cost and its sole discretion, provided that the enforcing Party shall notify the other Party in writing promptly upon becoming aware of such Infringement.

(f) Any recoveries resulting from enforcement action relating to a claim of Product Infringement shall be first applied pro rata against payment of each Party's costs and expenses in connection therewith. Any such recoveries in excess of such costs and expenses (the "**Remainder**") shall be shared by the Parties as follows:

(i) if Allogene is the enforcing Party, the Remainder shall be allocated [\*\*\*] percent ([\*\*\*]%) to Allogene and [\*\*\*] percent ([\*\*\*]%) to Notch; and

(ii) if Notch is the enforcing Party, the Remainder shall be allocated [\*\*\*] percent ([\*\*\*]%) to Notch and [\*\*\*] percent ([\*\*\*]%) to Allogene.

## 9. CONFIDENTIALITY

9.1 **Confidentiality; Exceptions.** Except to the extent expressly authorized by this Agreement or otherwise agreed by the Parties in writing, each Party (the "**Receiving Party**") agrees that it shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as provided for in this Agreement any Confidential Information of the other Party (the "**Disclosing Party**"). The term "**Confidential Information**" will mean all information and materials of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are transferred, disclosed or made available to the Receiving Party by or on behalf of the Disclosing Party in connection with this Agreement or the Prior Confidentiality Agreement, including any of the foregoing of Third Parties. The Joint Technology and the terms of this Agreement shall be the Confidential Information of both Parties, such that each Party shall be deemed to be a Receiving Party with respect thereto. Results, data and other information arising from the Research Plan or related to any CAR Product Directed Against an Exclusive Target that is Controlled by Notch and licensed to Allogene hereunder shall, subject to the licenses granted hereunder, be the Confidential Information of both Parties.

9.2 **Exceptions.** Notwithstanding the foregoing, the Receiving Party's obligations under Section 9.1 shall not apply to information or materials to the extent that the Receiving Party can establish by competent evidence that such information or material:

(a) was already rightfully known to or possessed by the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality, at the time of disclosure hereunder;

(b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party or any of its Affiliates;

(c) became generally available to the public or otherwise part of the public domain after its disclosure hereunder other than through any act or omission of the Receiving Party or any of its Affiliates in breach of this Agreement or the Prior Confidentiality Agreement;

(d) was independently developed by employees, agents or contractors of the receiving Party or any of its Affiliates without use of or reference to the Disclosing Party's Confidential Information as demonstrated by documented evidence prepared contemporaneously with such independent development; or

(e) was disclosed to the Receiving Party or any of its Affiliates, other than under an obligation of confidentiality, by a Third Party who had the right to disclose such information without restriction.

**9.3 Authorized Use and Disclosure.** In addition to the rights granted in Article 5, the Receiving Party may use and disclose the Disclosing Party's Confidential Information as follows:

(a) to its and its Affiliates' officers, directors, employees, agents, contractors and advisors who are under legally enforceable obligations of confidentiality and non-use at least as stringent as those herein and who reasonably require access to such information for purposes of this Agreement;

(b) complying with Applicable Laws, orders of a court, or the securities laws and regulations applicable to the public sale of securities; provided, however, that the Receiving Party shall, to the extent legally permissible and practicable, give reasonable advance notice to the Disclosing Party of such disclosure requirement and, shall use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed;

(c) such disclosure is reasonably necessary (i) to comply with the requirements of Regulatory Authorities with respect to obtaining and maintaining Regulatory Approval of a Product, (ii) to Prosecute and Maintain Patent Rights hereunder; or (iii) for prosecuting or defending litigation as contemplated by this Agreement; or

(d) as expressly agreed by the Disclosing Party.

**9.4 Prior Confidentiality Agreement.** As of the Effective Date, this Agreement terminates, supersedes and replaces the Prior Confidentiality Agreement with respect to information disclosed thereunder. Nothing herein shall release either Party for any liability incurred under the Prior Confidentiality Agreement prior to the Effective Date.

**9.5 Agreement Terms.**

(a) Each Party agrees not to disclose to any Third Party any non-public terms and conditions of this Agreement without the prior written approval of the other Party, except to advisors (including financial advisors, attorneys and accountants) and to potential and

existing investors, collaborators, partners, licensees, acquirers, lenders, or investment bankers under circumstances that reasonably protect the confidentiality thereof, and except as permitted pursuant to [Section 10.2](#). Allogene and Notch agree to issue a press release mutually agreed upon by the Parties, and either Party may publicly disclose the information contained in such press release without the need for further written approval by the other Party. Allogene shall have the sole right to disclose the Exclusive Targets, provided that Notch shall be permitted to disclose to any Third Party, without identifying Allogene, that an Exclusive Target is unavailable for the grant of rights to such Third Party.

(b) Each Party acknowledges that the other Party may be obligated to file a copy of this Agreement with the U.S. Securities and Exchange Commission (the “SEC”) or other applicable entity having regulatory authority over such Party’s securities or the exchange thereof, as a material agreement of such Party. Each Party shall be entitled to make such a required filing, provided that it requests confidential treatment of certain commercial terms and sensitive technical terms hereof to the extent such confidential treatment is reasonably available, and to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed. In the event of any such filing, the filing Party will provide the other Party with a copy of this Agreement marked to show provisions for which the filing Party intends to seek confidential treatment and shall reasonably consider and incorporate the other Party’s timely comments thereon to the extent consistent with the legal requirements governing redaction of information from material agreements that must be publicly filed. The other Party will as promptly as practical provide any such comments. Each Party recognizes that Applicable Laws and SEC policies and regulations to which the other Party is and may become subject to may require the other party to publicly disclose certain terms of this Agreement that such Party may prefer not be disclosed, and that the other Party is in all cases entitled hereunder to make such required disclosures to the extent necessary to comply with such Applicable Laws and SEC policies and regulations, as determined in good faith by the other Party’s counsel.

9.6 **Term of Obligations of Confidentiality and Non-use.** The obligations of confidentiality and non-use under this Agreement shall expire [\*\*\*] years from the termination or expiration of this Agreement.

#### 9.7 **Publication.**

(a) Rights. If either Party wishes to publish the Confidential Information of the other Party, the Party desiring to publish such information (“**Publishing Party**”) shall notify the other Party (“**Non-Publishing Party**”) in writing at least [\*\*\*] days prior to any proposed disclosure. During such at least [\*\*\*] day reviewing period, if the Non-Publishing Party notifies the Publishing Party that it wishes to (a) remove its Confidential Information from such proposed publication or presentation, then the Publishing Party shall remove such Confidential Information from such proposed publication or presentation; (b) request a reasonable delay in publication or presentation in order to protect patentable information, then the Publishing Party shall delay the publication or presentation for a period of no more than [\*\*\*] days to enable patent applications to be filed in accordance with [Article 8](#) protecting Inventions disclosed in such publication or presentation, or (c) in the case that Allogene is the Non-Publishing Party, prohibit the proposed publication or presentation from proceeding, then

the Publishing Party shall comply with such request. For clarity, if the Non-Publishing Party fails to notify the Publishing Party during the [\*\*\*]-day reviewing period as provided under this Section, the Publishing Party shall be free to proceed with the proposed publication or presentation of such Confidential Information.

(b) **Cooperation.** Authorship of all publications and presentations of data, results or information arising from the Research Program will be based on contributions to the Research Program in accordance with industry standards and journal requirements. Each Party agrees to work in good faith with the other Party with respect to any such publication or presentation reasonably requested by such other Party.

9.8 **Injunction.** Each Party shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to seek an injunction, in any court of competent jurisdiction, enjoining or restraining the other Party and/or its Affiliates from any violation or threatened violation of this Article 9.

## 10. **WARRANTIES;**

10.1 **Mutual Representations and Warranties.** Each Party represents and warrants to the other Party as of the Effective Date that:

(a) it is duly organized and validly existing under the laws of the jurisdiction of its incorporation, and it has the full right, power and authority to enter into this Agreement and to perform its obligations hereunder;

(b) this Agreement has been duly executed by it and is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, nor violate any material law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it; and

(c) it has obtained or will obtain written agreements from each of its employees, consultants, and contractors who perform activities under the Research Plan pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign Inventions in a manner consistent with the provisions of this Agreement.

10.2 **Notch Representations and Warranties.** Notch represents and warrants to Allogene as of the Effective Date that, except as set forth in Schedule 10.2:

(a) Notch has full legal or beneficial title and ownership of, or an exclusive license to, the Notch Technology (excluding the Joint Technology) as is necessary to grant the licenses (or sublicenses) to Allogene to such Notch Technology that Notch purports to grant pursuant to this Agreement. Exhibit C is a complete and accurate listing of all Notch Patents existing as of the Effective Date.

(b) Exhibit G is a complete and accurate listing of all Notch Third Party In-Licenses pursuant to which Notch or its Affiliates have obtained rights to the Notch Technology as of the Effective Date, and Notch has shared with Allogene a complete and



accurate copies of all such agreements. Each such agreement is in effect and is valid and binding on Notch or its Affiliates, enforceable in accordance with its terms, and neither Notch nor any of its Affiliates, nor to the knowledge of Notch, any other party thereto, is in material breach of, or material default under, any such agreement, and no event has occurred that, with the giving of notice or lapse of time or both, would constitute a material breach or material default by Notch or any of its Affiliates thereunder;

(c) None of the Notch Technology is subject to, any liens or encumbrances, and Notch has not granted to any Third Party any license or other right with respect to any Notch Technology that would conflict with the rights and licenses granted to Allogene pursuant to this Agreement. No patent application or registration within the Notch Patents is subject of any pending interference, opposition, cancellation, inter partes review, ex parte reexamination, post grant review, invalidity proceeding including nullity actions or patent protest;

(d) Notch is not a party to any current or anticipated legal action, including inventorship disputes, suit or proceeding relating to the Notch Technology;

(e) All employees and contractors of Notch or its Affiliates involved in the creation of any Notch Technology have assigned all right, title and interest in and to the Intellectual Property Rights relating to such Notch Technology to Notch or to an entity that is obligated to assign such Intellectual Property Rights to Notch;

(f) Notch has not received any communication from any Third Party claiming that: (i) any of the Notch Patents are invalid or unenforceable; (ii) any of the Notch Know-How has been misappropriated; or (iii) the manufacture, use, import, offer for sale, and sale of Products intended to be developed under the Research Program infringes or misappropriates or would infringe or misappropriate any Intellectual Property Rights of any Third Party; and

(g) to Notch's knowledge as of the Effective Date, the practice of the Notch Patents and the use of the Notch Know-How as contemplated under the initial Research Plan as of the Effective Date, will not infringe a Third Party's Intellectual Property Rights; provided that, for clarity, Notch gives no representation or warranty as to non-infringement with respect to any derivation of stem cell lines or any genetic engineering or gene editing of stem cell lines.

**10.3 Notch Covenants.** Notch covenants that all individuals and entities that conduct any portion of the Research Plan, prior to conducting such work, shall have entered into written agreements requiring that such individual or entity shall assign all right, title and interest in and to, or grant to Notch an exclusive (even as to such individual or entity), sublicensable (through multiple tiers), world-wide, fully paid-up license with respect to Products under, the Intellectual Property Rights relating to all Know-How and Inventions arising from such work to Notch or to an entity that is obligated to assign or license such Intellectual Property Rights to Notch, provided that Notch may grant Academic Use Rights to such an entity with notice to Allogene.

#### **10.4 Mutual Covenants.**

(a) No Debarment. In the course of conducting the Research Program and the Exploitation of Products hereunder, neither Party nor its Affiliates shall use any employee or consultant who has been debarred by any Regulatory Authority, or, to such Party's or its Affiliates' knowledge, is the subject of debarment proceedings by a Regulatory Authority.

Each Party shall notify the other Party promptly upon becoming aware that any of its or its Affiliates' employees or consultants has been debarred or is the subject of debarment proceedings by any Regulatory Authority.

(b) Compliance. Each Party and its Affiliates shall comply in all material respects with all Applicable Laws (including all anti-corruption and anti-bribery laws) in relation to the conduct of the Research Program and performance of its obligations under this Agreement, including (in the case of Allogene) the Exploitation of Products hereunder.

10.5 **Warranty Disclaimer**. EXCEPT AS SET FORTH IN THIS ARTICLE 10, NOTCH AND ALLOGENE EXPRESSLY DISCLAIM ANY WARRANTIES OR CONDITIONS, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO THE SUBJECT MATTER OF THIS AGREEMENT, INCLUDING ANY WARRANTY OF MERCHANTABILITY, NONINFRINGEMENT, OR FITNESS FOR A PARTICULAR PURPOSE.

## 11. INDEMNITY; LIABILITY; INSURANCE

### 11.1 Indemnification.

(a) Indemnification by Notch. Notch hereby agrees to defend, hold harmless and indemnify (collectively, "**Indemnify**") Allogene and its Affiliates, and its and their respective agents, directors, officers and employees (each, an "**Allogene Indemnitee**") from and against any Claims against any Allogene Indemnitee to the extent arising out of any negligence or intentional misconduct of any Notch Indemnitee or breach of this Agreement (including of any representation or warranty) by any Notch Indemnitee. Notch's obligation to Indemnify the Allogene Indemnitees pursuant to this subsection (a) shall not apply to the extent that any such Claims arise out of (A) Allogene's breach of this Agreement or any negligence or intentional misconduct of any Allogene Indemnitee, or (B) any activity set forth in subsection (b) below for which Allogene is obligated to indemnify the Notch Indemnitees.

(b) Indemnification by Allogene. Allogene hereby agrees to Indemnify Notch and its Affiliates, and its and their respective agents, directors, officers and employees (each, a "**Notch Indemnitee**") from and against any and all Claims against any Notch Indemnitee to the extent arising out of: (i) Allogene's Exploitation of Products or the exercise by or under the authority of Allogene of the rights and licenses granted to Allogene under this Agreement; or (ii) any negligence or intentional misconduct of any Allogene Indemnitee or breach of this Agreement (including of any representation or warranty) by any Allogene Indemnitee. Allogene's obligation to Indemnify the Notch Indemnitees pursuant to this subsection (b) shall not apply to the extent that any such Claims arise out of (A) Notch's breach of this Agreement or any negligence or intentional misconduct of any Notch Indemnitee, or (B) any activity set forth in subsection (a) above for which Notch is obligated to indemnify the Allogene Indemnitees.

11.2 **Procedures**. To be eligible to be Indemnified hereunder, the indemnified Party shall provide the indemnifying Party with prompt written notice of the Claim giving rise to the indemnification obligation pursuant to Section 11.1 and the exclusive ability to defend (with the reasonable cooperation of the indemnified Party) or settle any such claim; provided, however,

that any failure or delay to notify shall not excuse any obligation of the indemnifying Party except to the extent the indemnifying Party is actually prejudiced thereby. The indemnifying Party shall not enter into any settlement that admits fault, wrongdoing or damages without the indemnified Party's written consent, such consent not to be unreasonably withheld or delayed. The indemnified Party shall have the right to participate, at its own expense and with counsel of its choice, in the defense of any claim or suit that has been assumed by the indemnifying Party, provided that the indemnifying Party shall have no obligations with respect to any Claims resulting from the indemnified Party's admission, settlement or other communication without the prior written consent of the indemnifying Party.

11.3 **Insurance.** Each Party shall maintain in full force and effect during the Term, and for a period of not less than [\*\*\*] years thereafter, valid and collectible insurance policies providing reasonable liability insurance coverage to protect against potential liabilities and risk arising out of activities to be performed under this Agreement.

11.4 **Limitation of Liability.** EXCEPT WITH RESPECT TO (A) A BREACH OF EACH PARTY'S CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 9, OR (B) THE PARTIES' INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 11, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INDIRECT, OR INCIDENTAL DAMAGES ARISING OUT OF OR RELATED TO THIS AGREEMENT, INCLUDING LOSS OF PROFITS OR ANTICIPATED SALES, HOWEVER CAUSED, ON ANY THEORY OF LIABILITY AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

## 12 TERM; TERMINATION

12.1 **Term of Agreement.** The term of this Agreement shall commence on the Effective Date, and, unless terminated earlier as provided in the remainder of this Article 13, shall continue in full force and effect, on a country-by-country and Product-by-Product basis, until the expiration of all of Allogene's payment obligations under Article 6 (the "**Term**"), after which time Allogene shall retain a perpetual, irrevocable, exclusive license, sublicenseable through multiple tiers, to any Intellectual Property Rights licensed to Allogene pursuant to the terms of this Agreement during the Term, solely within the scope of the licenses granted to Allogene herein during the Term.

12.2 **Termination by Allogene.** Subject to Section 13.6, Allogene may terminate this Agreement for any reason at any time in its entirety or on a Product-by-Product basis upon ninety (90) days' written notice to Notch. Upon any termination by Allogene for convenience, all licenses and other rights granted to Allogene pursuant to this Agreement shall terminate as of the effective date of such termination, provided that if such termination is only with respect to a specific Product(s), then such licenses and rights shall terminate only with respect to such Product(s).

12.3 **Termination for Material Breach.** Either Party may terminate this Agreement by written notice referencing this Section 12.3 and specifying the breach to the other Party if the other Party is in material breach of its material obligations under this Agreement and has not cured such breach within ninety (90) days (or thirty (30) days in the case of payment breaches) after notice requesting cure of the breach; provided, however, that in the event of a good faith

dispute with respect to the existence of a material breach, this Agreement shall not be terminated unless it is finally determined under Article 13 that this Agreement was materially breached, and, the breaching Party fails to cure such breach within thirty (30) days after such determination.

**12.4 Termination for Insolvency.** If, at any time during the Term (i) a case is commenced by or against either Party under Title 11, United States Code, as amended, or analogous provisions of Applicable Law outside the United States (the “**Bankruptcy Code**”) and, in the event of an involuntary case under the Bankruptcy Code, such case is not dismissed within sixty (60) days after the commencement thereof, (ii) either Party files for or is subject to the institution of bankruptcy, liquidation or receivership proceedings (other than a case under the Bankruptcy Code), (iii) either Party assigns all or a substantial portion of its assets for the benefit of creditors, (iv) a receiver or custodian is appointed for either Party’s business, or (v) a substantial portion of either Party’s business is subject to attachment or similar process; then, in any such case ((i), (ii), (iii), (iv) or (v)), the other Party may terminate this Agreement upon written notice to the extent permitted under Applicable Law.

#### **12.5 Effect of Termination.**

(a) Accrued Obligations. Expiration or termination of this Agreement for any reason shall not release either Party of any obligation or liability which, at the time of such expiration or termination, has already accrued to such Party or which is attributable to a period prior to such expiration or termination. In addition, Sections 4.4, 4.6, 6.3 (solely with respect to Research Costs incurred prior to the effective date of termination), 6.11 (solely with respect to Product sales occurring prior to the effective date of termination), 6.12, 6.13, 6.14, 7.1, 7.2, 10.5 and 12.5, and Articles 9, 11, 13 and 14, shall survive any termination or expiration of this Agreement.

(b) Non-Exclusive Remedy. Notwithstanding anything herein to the contrary, termination of this Agreement by a Party shall be without prejudice to other remedies such Party may have at law or in equity.

#### (c) Consequences of Certain Terminations.

(iii) If this Agreement is terminated pursuant to Section 12.2 by Allogene, Section 12.3 by either Party, or Section 12.4 by either Party, all licenses and other rights granted to Allogene pursuant to this Agreement shall terminate as of the effective date of termination, provided that if a termination by Allogene pursuant to Section 12.2 is not for this Agreement in its entirety, then the scope of such termination shall be limited to the particular Product(s) terminated pursuant to Section 12.2;

(iv) If Allogene has the right to terminate this Agreement pursuant to Section 12.3, then in lieu of exercising such termination right Allogene shall be entitled to retain all licenses and other rights granted to it pursuant to this Agreement subject to all financial provisions and other obligations set forth herein, provided that in such event Allogene may also seek any other remedies that Allogene may have at law or in equity in respect of the applicable breach hereof by Notch.

(d) Return of Materials; Regulatory Documents; Reversion License. Upon termination or expiration of this Agreement, each Party shall return to the other Party or destroy

all Confidential Information and materials (including any Materials) provided to it by the other Party and all copies and embodiments thereof, other than such Confidential Information and materials to which such Party retains an ongoing right to use. Notwithstanding the foregoing, each Party may retain one copy of the other Party's Confidential Information in its confidential files solely for archival purposes. In addition, upon termination, other than for termination by Allogene pursuant to Section 12.3 or 12.4, and at Notch's request, Allogene shall exclusively negotiate with Notch for a period of [\*\*\*] days following the date of such termination for a sale or license to Notch of one or more of the Products developed hereunder.

### 13. DISPUTE RESOLUTION

13.1 **Disputes.** Subject to Section 13.3, if the Parties or the JDC are unable to resolve any dispute arising out of or in connection with this Agreement, either Party may, by written notice to the other, have such dispute referred to the CEOs of each of Notch and Allogene or their respective equivalents, or designees for attempted resolution by good faith negotiations within [\*\*\*] Business Days after such notice is received. In such event, the Parties shall cause their respective officers or their designees to meet (face-to-face or by teleconference) and be available to attempt to resolve such issue. If the Parties should resolve such dispute, a memorandum setting forth their agreement shall be prepared and signed by both Parties at either Party's request. If the Parties are unable to resolve any dispute that is related to the Research Plan, Allogene shall have the final decision-making authority with respect to such dispute. Notwithstanding the foregoing, Allogene shall have no authority to require Notch to incur costs that are not included within the Research Budget or otherwise subject to reimbursement by Allogene, without Notch's prior written consent, and Allogene shall have no final decision-making authority to determine whether or not any payment due hereunder (including any milestone payment hereunder) has been earned or is payable, which payment disputes shall be subject to resolution in accordance with Section 13.2.

13.2 **Arbitration.** Subject to Sections 13.1 and 13.3, all disputes arising out of or in connection with this Agreement, including any question regarding its formation, existence, validity or termination, shall be finally settled by arbitration pursuant to this Section 13.2. Any arbitration under this Section 13.2 shall be held in San Francisco, California, and administered by JAMS pursuant to its Comprehensive Arbitration Rules and Procedures (the "**Rules**") by three (3) arbitrators appointed in accordance with such Rules. The arbitrators shall allow reasonable discovery, in an amount determined by the arbitrator to be necessary in view of the issues in dispute. The Parties shall use good faith efforts to complete arbitration under this Section 14.2 within [\*\*\*] months following the initiation of such arbitration. The arbitrators shall establish reasonable additional procedures to facilitate and complete such arbitration within such [\*\*\*] month period. The costs of such arbitration shall be shared equally by the Parties, and each Party shall bear its own expenses in connection with the arbitration; provided that the arbitrators shall have discretion to award all or any part of the costs of the arbitration, including reasonable attorneys' fees, to the prevailing Party. Judgment on the award may be entered in any court of competent jurisdiction. The existence of and proceedings in the arbitration shall be considered the Confidential Information of both Parties and shall be subject to the terms of Article 9.

13.3 **Patents; Injunctive Relief.** Any dispute, controversy, or claim relating to the scope, validity, enforceability, or infringement of any Patent Rights covering the manufacture,

use, or sale of any Product shall be submitted to a court of competent jurisdiction in the country or jurisdiction in which such patent or trademark rights were granted or arose. Nothing herein shall prevent either Party from seeking at any time a preliminary injunction or temporary restraining order **in any court of competent jurisdiction in order to protect its interests.**

#### **14. MISCELLANEOUS**

14.1 **Governing Law.** This Agreement shall be governed in all respects by the laws of the State of New York exclusively without regard to any conflict of law rule that would result in the application of the laws of any jurisdiction other than the State of New York.

14.2 **Force Majeure.** Except with respect to payment of money, neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by earthquake, riot, civil commotion, war, terrorist acts, strike, flood, or governmental acts or restriction, or other cause that is beyond the reasonable control of the respective Party. The Party affected by such force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use commercially reasonable efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. If the performance of any such obligation under this Agreement is delayed owing to such a force majeure for any continuous period of more than [\*\*\*] days, the Parties shall consult with respect to an equitable solution, including the possibility of the mutual termination of this Agreement.

14.3 **Relationship.** The Parties agree that the relationship of Notch and Allogene established by this Agreement is that of independent contractors. Furthermore, the Parties agree that this Agreement does not, is not intended to, and shall not be construed to, establish an employment, agency or any other relationship. Except as may be specifically provided herein, neither Party shall have any right, power or authority, nor shall they represent themselves as having any authority to assume, create or incur any expense, liability or obligation, express or implied, on behalf of the other Party, or otherwise act as an agent for the other Party for any purpose. Neither Party shall report the relationship between the Parties arising under this Agreement as a partnership for United States tax purposes without the prior written consent of the other Party unless required by a final “determination” as defined in Section 1313 of the United States Internal Revenue Code of 1986, as amended.

14.4 **Assignment.** This Agreement shall not be assignable by either Party to any Third Party without the written consent of the other Party and any such attempted assignment shall be void. Notwithstanding the foregoing, either Party may assign this Agreement, without the written consent of the other Party, to its Affiliate or an entity that acquires all or substantially all of the business or assets of such Party to which this Agreement pertains (whether by merger, reorganization, acquisition, sale or otherwise), and agrees in writing to be bound by the terms and conditions of this Agreement. No assignment or transfer of this Agreement shall be valid and effective unless and until the assignee/transferee agrees in writing to be bound by the provisions of this Agreement. The terms and conditions of this Agreement shall be binding on and inure to the benefit of the permitted successors and assigns of the Parties, provided that, the exclusivity provisions applicable to Notch pursuant to Section 4.5 shall not apply to any acquiror or successor-in-interest to Notch or any Affiliate of any such acquiror or successor-in-interest, in

any case that was not an Affiliate of Notch prior to an applicable Change of Control transaction involving Notch (but, for the avoidance of doubt, the exception from the exclusivity provisions set forth in this proviso shall not permit the use of any Notch Technology for activities that would otherwise be restricted by the exclusivity provisions applicable to Notch pursuant to Section 4.5). Except as expressly provided in this Section, any attempted assignment or transfer of this Agreement shall be null and void.

14.5 **Change in Control.** Notwithstanding Section 14.4, Notch shall provide written notice to Allogene upon its intention to sell all or substantially all of its business or assets (whether by merger, reorganization, acquisition, sale or otherwise) (a “**CIC Transaction**”) at least [\*\*\*] days prior to entering into a binding agreement for such sale or exclusivity agreement regarding the negotiation of such sale.

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

14.7 **Waiver.** Neither Party may waive or release any of its rights or interests in this Agreement except in writing. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver of such condition or term or of another condition or term.

14.8 **Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall make specific reference to this Agreement, and shall be addressed to the appropriate Party at the address specified below or such other address as may be specified by such Party in writing in accordance with this Section, and shall be deemed to have been given for all purposes (a) when received, if hand-delivered or sent by a reputable overnight delivery service, (b) on the day of sending by email (with receipt confirmation), or (c) three (3) days after mailing, if mailed by first class certified or registered mail, postage prepaid, return receipt requested.

If to Notch, addressed to:

Notch Therapeutics Inc.  
Attn: President  
40 King Street West, Suite 2100  
Toronto, Ontario M5H 3C2  
Canada  
Email:

If to Allogene, addressed to:

Allogene Therapeutics, Inc.  
Attn: General Counsel

210 E. Grand Avenue  
South San Francisco, CA 94080  
USA  
Email:

14.9 **Severability.** Any term or provision of this Agreement that is held to be invalid, void, or unenforceable in any situation in any jurisdiction will not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the invalid, void, or unenforceable term or provision in any other situation or in any other jurisdiction. If any term or provision of this Agreement is declared invalid, void, or unenforceable, the Parties agree that the authority making such determination will have the power to and shall, subject to the discretion of such authority, reduce the scope, duration, area or applicability of the term or provision, to delete specific words or phrases, or to replace any invalid, void, or unenforceable term or provision with a term or provision that is valid and enforceable and that comes closest to expressing the original intention of the invalid or unenforceable term or provision.

14.10 **Interpretation.** The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation;” (b) the word “day” or “year” means a calendar day or year unless otherwise specified; (c) the word “notice” shall mean notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to this Agreement (including any Exhibits); (e) the word “or” shall be construed as the inclusive meaning identified with the phrase “and/or;”(f) provisions that require that a Party, the Parties or a committee hereunder “agree,” “consent” or “approve” or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (g) words of any gender include the other gender; (h) words using the singular or plural number also include the plural or singular number, respectively; (i) references to any Applicable Laws, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement Applicable Laws thereto; and (j) neither Party or its Affiliates shall be deemed to be acting “on behalf of” or “under authority of” the other Party under this Agreement.

14.11 **Counterparts.** This Agreement may be executed in two or more counterparts (whether delivered by email via .pdf format, facsimile or otherwise), each of which will be considered one and the same agreement and will become effective when counterparts have been signed by each of the Parties and delivered to the other Party.

14.12 **Entire Agreement.** This Agreement with its Exhibits and Schedules (a) constitutes the entire agreement and supersedes, as of the Effective Date, all prior and contemporaneous agreements, negotiations, arrangements and understandings, both written and oral, between the Parties with respect to the subject matter hereof, and (b) is not intended to confer upon any person or entity, other than the Parties, any rights, benefits, or remedies of any



nature whatsoever. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by the respective authorized officers of the Parties.

*[Signature Page Follows]*

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

**ALLOGENE THERAPEUTICS, INC. NOTCH THERAPEUTICS INC.**

By: /s/ David Chang By: /s/ Timothy Key

Name: David Chang, M.D., Ph.D. Name: Timothy Key, PhD

Title: CEO and President Title: Director

**List of Exhibits**

**Exhibit A – Initial Targets**

**Exhibit B – Notch Microbead Technology**

**Exhibit C – Notch Patents**

**Exhibit D – ROFN Targets**

**Exhibit E – Initial Research Plan**

**Exhibit F – Cellectis Technology Targets**

**Exhibit G – Notch Third Party In-Licenses**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We consent to the incorporation by reference in the following Registration Statements:

- a. Registration Statements (Forms S-8 Nos. 333-227965 and 333-230164) Amended and Restated 2018 Equity Incentive Plan, and 2018 Employee Stock Purchase Plan of Allogene Therapeutics, Inc.
- b. Registration Statement on Forms S-3 No. 333-234516, of Allogene Therapeutics, Inc.;

of our reports dated February 27, 2020, with respect to the financial statements of Allogene Therapeutics, Inc. and the effectiveness of internal control over financial reporting of Allogene Therapeutics, Inc. included in this Annual Report (Form 10-K) of Allogene Therapeutics, Inc. for the year ended December 31, 2019.

/s/ Ernst & Young LLP

San Jose, California  
February 27, 2020

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

Date: February 27, 2020

By: /s/ David Chang, M.D., Ph.D.

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

Date: February 27, 2020

By: /s/ Eric Schmidt, Ph.D

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

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

In connection with the Annual Report of Allogene Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019, to which this Certification is attached as Exhibit 32.1, 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 certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: February 27, 2020

By: /s/ David Chang, M.D., Ph.D.

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

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Allogene Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

**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 Annual Report of Allogene Therapeutics, Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2019, to which this Certification is attached as Exhibit 32.2, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Eric Schmidt, Ph.D., Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

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

Date: February 27, 2020

By: /s/ Eric Schmidt, Ph.D

---

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

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Allogene Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.