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, 2023

OR

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

Commission File Number 001-39409

ALLOVIR, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**83-1971007**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1100 Winter Street Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 433-2605

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 $0.0001 per share	ALVR	The Nasdaq Global Select Market

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

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

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 was $265.4 million based on the closing price of the shares of common stock on The Nasdaq Global Select Market on June 30, 2023, the last business day of the registrant's most recently completed second quarter. In determining the market value of non-affiliate common stock, shares of the Registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock, par value $0.0001 per share, outstanding as of March 8, 2024 was 114,869,175.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2024 Annual Meeting of Stockholders, or the Proxy Statement, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the Registrant's fiscal year end of December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

Summary of Material Risks Associated with Our Business

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "Risk Factors." These risks include, but are not limited to, the following:

- We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future could have negative consequences.
- Even if we successfully consummate any transaction from our strategic assessment, including, but not limited to, in-licensing and/or out-licensing, a merger, sale, and/or divestiture of assets, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.
- If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.
- If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.
- We are a clinical-stage cell therapy company and we have incurred net losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We depend substantially on intellectual property licensed from third parties, including Baylor College of Medicine, or BCM, and termination of any of these licenses could result in the loss of significant rights, which would harm our business.
- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and manufacturing process, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.
- We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts.
- We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We are early in our development efforts and have only a small number of product candidates in clinical development. All of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be materially harmed.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.
- The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Our existing product candidates in clinical trials, and any other product candidate we advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.
- Our product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We and our third-party partners are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.
- We intend to develop an efficient and highly productive manufacturing supply chain for our allogeneic, off-the-shelf single- and multi-virus specific T, or VST, cell therapies. Delays in process performance qualification to validate the drug product manufacturing process could delay regulatory approvals, our development plans and thereby limit our ability to generate revenues.
- We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- The trading price of our common stock may be volatile.
- Our business could be adversely affected by the effects of health epidemics, like the COVID-19 pandemic, in regions where our contracted third parties, including contract research organizations, or CROs, and contract development and manufacturing organizations, or CMOs or CDMOs, have significant research, development or manufacturing facilities, concentrations of clinical trial sites or other business operations, causing disruption in supplies and services.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled "Risk Factors" and the other information set forth in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes, as well as in other documents that we file with the SEC. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements, including but not limited to, statements about:

- our plans and expectations regarding our strategic alternative review process and the timing and success of such process regarding a potential transaction;
- timing of and costs or charges associated with our restructurings, and the savings benefits we expect to receive from those restructurings;
- success in retaining, or changes required in, our officers, key employees or directors;
- should we resume development of our product candidates, the success, cost, timing and potential indications of our product development activities and clinical trials, including the future clinical trials of posoleucel and ALVR106;
- the timing of our planned Investigational New Drug, or IND, submissions to the U.S. Food and Drug Administration, or FDA, for our product candidates, including ALVR107;
- the timing of the initiation, enrollment and completion of planned clinical trials;
- should we resume development of our product candidates, our plans to research, develop and commercialize our product candidates, including posoleucel, ALVR106, and ALVR107;
- the timing of the initiation, completion and outcomes of our preclinical studies;
- the costs of development of any of our product candidates or clinical development programs and our ability to obtain funding for our operations, including funding necessary to complete the clinical trials of any of our product candidates;
- our ability to successfully manufacture and distribute posoleucel, ALVR106 or any other future product or product candidate, should we resume development of our product candidates;
- the potential benefits of and our ability to maintain our collaboration with our existing collaborators, including BCM, and establish or maintain future collaborations or strategic relationships or obtain additional funding;
- the ability to maintain our existing license agreements, including Baylor College of Medicine, or BCM, and to license additional intellectual property relating to any future product candidates and to comply with our existing license agreements;
- our ability to attract and retain collaborators with development, regulatory and commercialization expertise;
- risks associated with a health epidemic like the COVID-19 pandemic, including the emergence of new COVID-19 variants, which may adversely impact our business and clinical trials;
- the size of the markets for our VST product candidates, and our ability to serve those markets;
- whether the results of our clinical trials will be sufficient to support domestic or foreign regulatory approvals for any of our product candidates;
- should we resume development of our product candidates, our ability to successfully commercialize our product candidates, including posoleucel and ALVR106;
- should we resume development of our product candidates, the rate and degree of market acceptance of our product candidates, including posoleucel and ALVR106;
- 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 or warnings in the label of any approved product we develop;
- 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 with respect to our product candidates or our competitors' products and product candidates;

- our reliance on third-party contract manufacturers and the performance of our third-party suppliers and manufacturers to manufacture and supply our product candidates for us;
- the success of competing therapies that are or become available;
- our ability to attract and retain key scientific or management personnel;
- our expectation about the period of time over which our existing capital resources will be sufficient to fund our operating expenses and capital expenditures;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act;
- our financial performance;
- the impact of laws and regulations;
- developments and projections relating to our competitors or our industry;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; 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 forward-looking statements by the words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," "will," or "would," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.

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.

You should read the section titled "Risk Factors" set forth in Part I, Item 1A of this Annual Report on Form 10-K for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

You should read this Annual Report on Form 10-K, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

PART I

Item 1. Business.

Overview

We are a cell therapy company developing highly innovative allogeneic T cell therapies to treat and prevent devastating viral diseases. Our innovative and proprietary virus-specific T cell, or VST, therapy platform allows AlloVir to generate off-the-shelf VSTs designed to restore immunity in patients with T cell deficiencies who are at risk from the life-threatening consequences of viral diseases. There is an urgent medical need for therapies to treat a large number of patients suffering from viral diseases who currently have limited or no treatment options. Our platform includes three innovative, allogeneic, off-the-shelf VST therapy candidates targeting 11 different devastating viruses. Our lead product candidate, posoleucel (previously referred to as Viralym-M or ALVR105), is a multi-VST therapy that targets six viruses: adenovirus, or AdV, BK virus, or BKV, cytomegalovirus, or CMV, Epstein-Barr virus, or EBV, human herpesvirus 6, or HHV-6 and JC virus, or JCV.

In December 2023, we announced the discontinuation of three Phase 3 registrational trials of posoleucel following separate, pre-planned Data Safety Monitoring Board, or DSMB, futility analyses that concluded the studies were unlikely to meet their primary endpoints. Specifically, we discontinued a multicenter, randomized, double-blind, placebo-controlled Phase 3 trial comparing posoleucel to placebo for the prevention of infection or disease due to AdV, BKV, CMV, EBV, HHV-6, or JCV in high-risk adult and pediatric patients after undergoing an allogeneic hematopoietic stem cell transplant. We also discontinued two multicenter, randomized, double-blind, placebo-controlled Phase 3 trials of posoleucel – one for the treatment of virus-associated hemorrhagic cystitis and the second for the treatment of adenovirus infection - both after allogeneic hematopoietic cell transplant.

In December 2023, we also announced that we would review the detailed datasets from those Phase 3 trials and launch a comprehensive review of strategic alternatives focused on maximizing stockholder value, including, but not limited to, a merger, sale, divestiture of assets, licensing, or other strategic transaction. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value, or that we will make any cash distributions to our stockholders.

In connection with the evaluation of strategic alternatives and in order to maximize capital preservation, we have implemented a plan to reduce our workforce by approximately 95%. This workforce reduction plan was approved in January 2024, and will take place primarily during the first quarter of 2024 and is expected to be substantially completed by April 15, 2024. In clinical trials conducted to date, we have treated more than 500 transplant patients with either single or multi-virus targeted allogeneic VSTs, and our product candidates have been generally well-tolerated and have been associated with clinical benefit. We believe that our allogeneic, off-the-shelf VSTs can benefit patients with other conditions characterized by T-cell deficiencies who are at high risk for life-threatening viral diseases, including immunocompromised cancer patients, the elderly and young children with immature immune systems.

Our proprietary VST manufacturing platform enables the rapid, robust and reproducible generation of single-virus and multi-virus specific cell therapeutic candidates for clinical use. Our VST production process selectively expands polyclonal (CD4+ helper and CD8+ cytotoxic) virus-targeted T-cell populations. The critical components of our off-the-shelf VST platform, for which patents are issued and/or pending, include:

- Methods of identifying immunodominant viral antigens in target viruses;
- Cytokin™, our selection algorithm to identify healthy donors from whom to generate VSTs that provide coverage to over 95% of patients in our targeted populations;
- Methods of rapidly and selectively expanding polyclonal VSTs *ex vivo*; and
- Cytomatch™, our algorithm to choose the appropriate partially HLA-matched off-the-shelf VST therapy to deliver to each patient.

We have applied this expertise in the development of additional product candidates that may benefit high-risk individuals:

- ALVR106 is our second off-the-shelf, multi-VST product candidate that we developed to target devastating respiratory diseases caused by human metapneumovirus, or hMPV, influenza, parainfluenza virus, or PIV, and respiratory syncytial virus, or RSV. A Phase 1b/2 proof of concept clinical study of ALVR106 has completed enrollment of patients in Part A of the trial. We have paused development of ALVR106, including discontinuing the trial pending the outcome of our review of strategic alternatives.
- ALVR107 is our preclinical stage product candidate designed to target hepatitis B, or HBV, infected cells and with the aim of curing chronic HBV infections. Preclinical and IND-enabling studies of ALVR107 to treat and cure HBV were completed

in 2022 to support advancement into a POC study. Clinical development of ALVR107 is currently paused pending the outcome of our review of strategic alternatives.

Our management team has significant experience in successfully advancing products from early-stage discovery through commercialization. Our Chief Executive Officer, Diana Brainard, has more than 20 years of experience in the biopharmaceutical industry and academic medicine. During her 10-year tenure at Gilead Sciences, Dr. Brainard served as the head of the virology therapeutic area, leading the development and launch of some of the most successful drugs of the last decade, including Sovaldi, Harvoni, Epclusa and Biktarvy. In 2020, she led the company-wide initiative to rapidly advance Veklury (remdesivir) to become the first and only antiviral to receive regulatory approval for the treatment of SARS-CoV-2, which earned her global recognition as one of the most influential people in the fight against SARS-CoV-2. Her industry career began at Merck, where she held positions in clinical pharmacology and experimental medicine. Dr. Brainard also serves as an Independent Director of Nektar Therapeutics and Affinia Therapeutics.

Vikas Sinha, our President and Chief Financial Officer, brings more than 25 years of experience in executive finance roles within the biopharmaceutical industry. He served as the Chief Financial Officer of Alexion Pharmaceuticals for more than 11 years, where he oversaw the global expansion of the company across 50 countries and revenue growth to more than $3 billion. Prior to joining Alexion, Mr. Sinha held various positions with Bayer AG across the world, including CFO, Bayer Pharma, North America and CFO, Bayer Yakuhin, Japan. He also serves as Chief Financial Officer of ElevateBio and an Independent Director and Audit Committee Chair at Verona Pharma.

To date, we have raised $156.9 million in aggregate gross proceeds through private financings, $317.7 million in aggregate gross proceeds through our IPO, which closed in August 2020, $126.6 million in aggregate gross proceeds through a registered direct offering in July 2022, and $75.0 million in aggregate gross proceeds through an underwritten public offering July 2023.

Our Pipeline

Our pipeline is comprised of three allogeneic off-the-shelf VST therapy candidates targeting 11 different viruses to treat and prevent life-threatening viral diseases. For each of these pipeline therapies, we have global development and commercialization rights. The chart below summarizes key information about our programs. As noted above, in December 2023, we announced the discontinuation of all three Phase 3 registrational trials of posoleucel.

Our Pipeline Targets 11 Devastating Viruses With No or Limited Treatment Options

	Candidate	Target Population	Target Indication
Multi-VST	Posoleucel (ALVR105)	Allogeneic-Hematopoietic Cell Transplant (Allo-HCT)	Multi-virus prevention*
			vHC treatment
			AdV treatment
		Kidney transplant	BKV treatment
		Solid organ transplant	Multi-virus prevention*
	ALVR106	Transplant patients	hMPV, Flu, PIV, RSV treatment
		High-risk general population	
Single VST	ALVR107	Chronic Hepatitis B	HBV cure

*Prevention of clinically significant infections or end-organ disease caused by adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpesvirus 6 (HHV-6), JC virus (JCV).
vHC = virus-associated Hemorrhagic Cystitis; hMPV = human Metapneumovirus; Flu = Influenza; PIV = Parainfluenza Virus; RSV = Respiratory Syncytial Virus; HBV = Hepatitis B Virus

- **Posoleucel.** An allogeneic, off-the-shelf VST therapy candidate targeting six common viruses: AdV, BKV, CMV, EBV, HHV-6 and JCV, which can lead to devastating viral disease in the allogeneic HCT population. Given that posoleucel is multi-VST product candidate, the therapy has multiple potential applications.

  Promising efficacy and safety results from the completed Phase 2 treatment and prevention trials in allogeneic HCT patients enabled the rapid progression of posoleucel into Phase 3 development. In the CHARMS Phase 2 POC treatment trial, 95% of allogeneic HCT patients with infections from one or more of the target viruses and who previously failed or were intolerant to conventional antiviral treatments, achieved a clinical response when treated with posoleucel therapy. In the Phase 2 multi-virus prevention trial, posoleucel demonstrated a substantial reduction in the expected rate of clinically significant viral infections or diseases, with 88% of patients remained free of clinically significant infections caused by any of the six viruses that posoleucel targets through the Week 14 primary endpoint.

  A Phase 2 POC trial of posoleucel to treat BK viremia in kidney transplant patients completed in 2022. Positive topline data from the BKV study were reported in February 2023, showing balanced safety across posoleucel and placebo groups and clinically meaningful greater viral load declines with posoleucel versus placebo.

  Based on the totality of supportive evidence in the allo-HCT patient population, we initiated three Phase 3 registrational trials of posoleucel – one for the treatment of virus-associated HC, one for the treatment of adenovirus infection and one for multi-virus prevention, all in HCT patients. In December 2023, we announced the discontinuation of all three Phase 3 registrational trials of posoleucel following separate, pre-planned DSMB futility analyses concluded the studies were unlikely to meet their primary endpoints based on the interim data reviewed by each DSMB.

- **ALVR106**. An allogeneic, off-the-shelf VST therapy candidate developed to target devastating diseases caused by four respiratory viruses: hMPV, influenza, PIV and RSV. A Phase 1b/2 proof of concept clinical study of ALVR106 has completed enrollment of patients in Part A of the trial. In December 2023, we paused development of ALVR106, including discontinuing the trial pending the outcome of our review of strategic alternatives.
- **ALVR107**. An allogeneic, off-the-shelf VST therapy candidate designed to target HBV-infected cells with the aim of curing chronic HBV infections. Preclinical and IND-enabling studies of ALVR107 to treat and cure HBV were completed in 2022 to support advancement into a proof of concept study. Clinical development of ALVR107 is currently paused pending the outcome of our review of strategic alternatives.

Our Strategy

As announced in December 2023, we have discontinued the three Phase 3 registrational trials of posoleucel following separate, pre-planned DSMB futility analyses concluded the studies were unlikely to meet their primary endpoints.

As also announced in December 2023, we are completing a comprehensive review of strategic alternatives focused on maximizing stockholder value, including, but not limited to, a merger, sale, divestiture of assets, licensing, or other strategic transaction. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value, or that we will make any additional cash distributions to our stockholders.

In connection with the evaluation of strategic alternatives and in order maximize capital preservation, we have implemented a plan to reduce our workforce by approximately 95%. This workforce reduction will take place primarily during the first quarter of 2024 and is expected to be substantially completed by April 15, 2024.

The Immune System and the Role of T Cells

In healthy individuals, the adaptive immune response forms a critical component of the body's natural defense system and provides protection against numerous disease-causing viruses, as depicted in the figure below. Certain types of T cells have an essential role in driving the immune response to viruses. The major role of CD8+ "cytotoxic" T cells is to kill virus-infected or otherwise diseased cells, while the major role of CD4+ "helper" T cells is to produce soluble proteins, known as cytokines, which produce direct antiviral effects and support CD8+ T-cell survival. CD4+ T cells can also signal other immune cell types, including antibody-producing B cells, thereby influencing the broader antiviral immune response. CD8+ and CD4+ T cells are vital components in maintaining adaptive immunity against many devastating viruses.

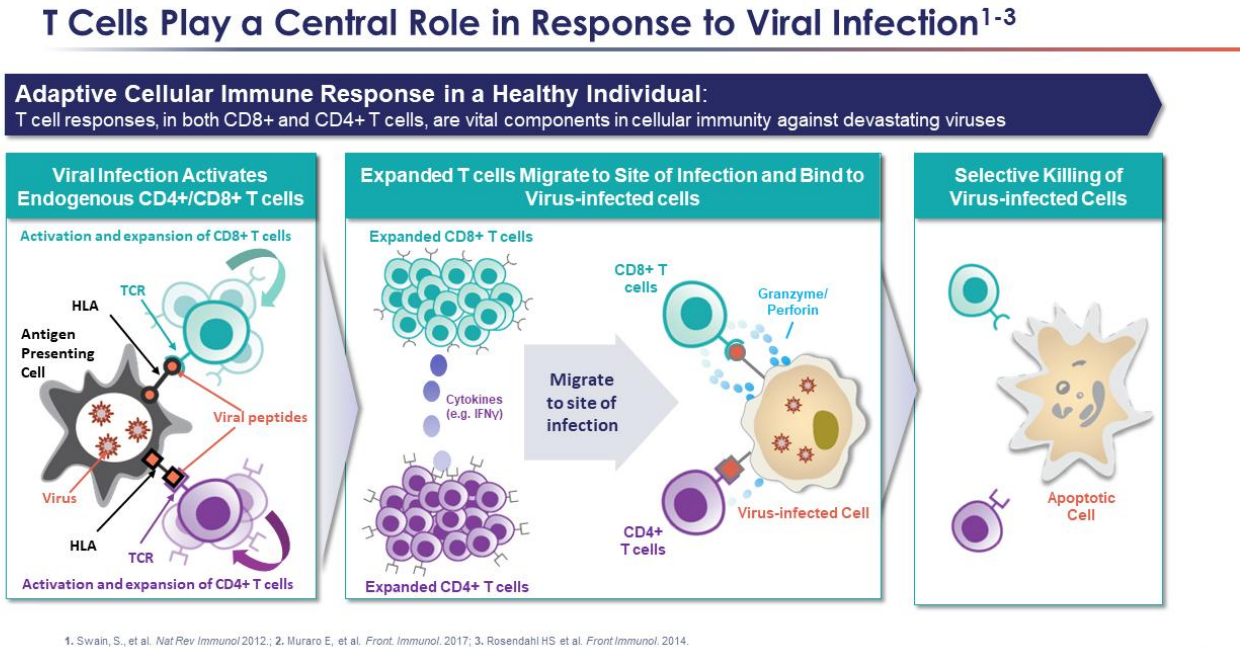

Figure 1. T cells play a central role in response to viral infection

T cells recognize viruses via their T-cell receptors, or TCRs, which selectively recognize "foreign" viral peptides displayed by a compatible "self" human leukocyte antigen, or HLA, proteins present on the surface of virus-infected cells or antigen presenting cells. Once T cells bind to the peptide-HLA complex, they become activated and start to multiply as the body mounts an immune response to control or eliminate the virus. In contrast, if the peptide displayed by the HLA allele is not "foreign" but instead from a "self" antigen, then T cells do not bind to the cell and no immune response is generated.

To be clinically effective, at least a portion of the infused, allogeneic, off-the-shelf VSTs must be compatible, or partially HLA matched, with the patient so that some of the infused T cells can bind to viral peptide-HLA complexes, resulting in selective antiviral effects against virus-infected cells.

While HLA alleles provide a defining feature of an individual's biology, there are only a limited number of unique HLA types among humans. This important characteristic has allowed us to develop allogeneic VSTs from donors who are carefully chosen to provide HLA coverage to the broad patient population at risk of devastating viral infections.

VST therapies are specifically designed to enhance and restore T-cell function. In patients with T-cell deficiencies, uncontrolled viral infection, replication and expansion can result in severe and devastating consequences.

Transplantation and Immunosuppression

There are two major types of transplant procedures: HCTs and SOTs. In each procedure, the immune system of the patient is suppressed or eliminated to prevent rejection of the transplanted cells or organs. In the case of HCT, this immunocompromised state is

typically temporary and resolves once the transplanted donor stem cells begin to replenish the cells of the immune system. In SOT, most patients require a high dose of immunosuppressive drugs for the first six months post-transplant and some degree of immunosuppressive treatment for the rest of their lives.

HCTs are clinical procedures used in the treatment of severe and life-threatening diseases primarily of the blood and immune systems, including some forms of leukemia and lymphoma, genetic diseases and other blood-based diseases. In HCTs, physicians remove diseased or, in the case of some genetic diseases, missing blood cells, along with the stem cells that lead to their formation. The physician then replaces the diseased or missing blood cells with healthy red and white blood cell-forming stem cells from donors. The process of destroying the defective cells, known as conditioning, also leads to the depletion of the patient's immune cells, leaving patients highly vulnerable to disease-causing viruses, which can become life-threatening due to their weakened immune systems. Patients can remain vulnerable for an extended period until the donor stem cells take up residence and begin to reconstitute a functional immune system. A key challenge in HCT is the identification of transplant material that is immunologically compatible with the patient. The selection of donors for HCT procedures requires that the donor's HLA antigens comprise a close match to those of the patient, as an exact match is not often available. Procedures using more stringent conditioning enable these patients to receive partially matched stem cells from allogeneic donors. This more stringent conditioning, known as myeloablative conditioning, leaves the patient extremely immunosuppressed and highly prone to potentially deadly viral diseases.

In up to 90% of allogeneic HCT patients, the suppressed immune system allows viruses that were previously in a latent, quiescent state to reactivate and more than 60% of allogeneic HCT patients experience a reactivation of more than one virus, including BKV, CMV, AdV, EBV and HHV-6, as depicted in the figure below. In healthy, immunocompetent individuals, these viruses typically lead to mild, self-limiting infections. However, in immunocompromised patients, once reactivated, each of these viruses has the potential to cause significant morbidity and even mortality. It is estimated that more than 20% of all deaths associated with HCTs are due to infections.

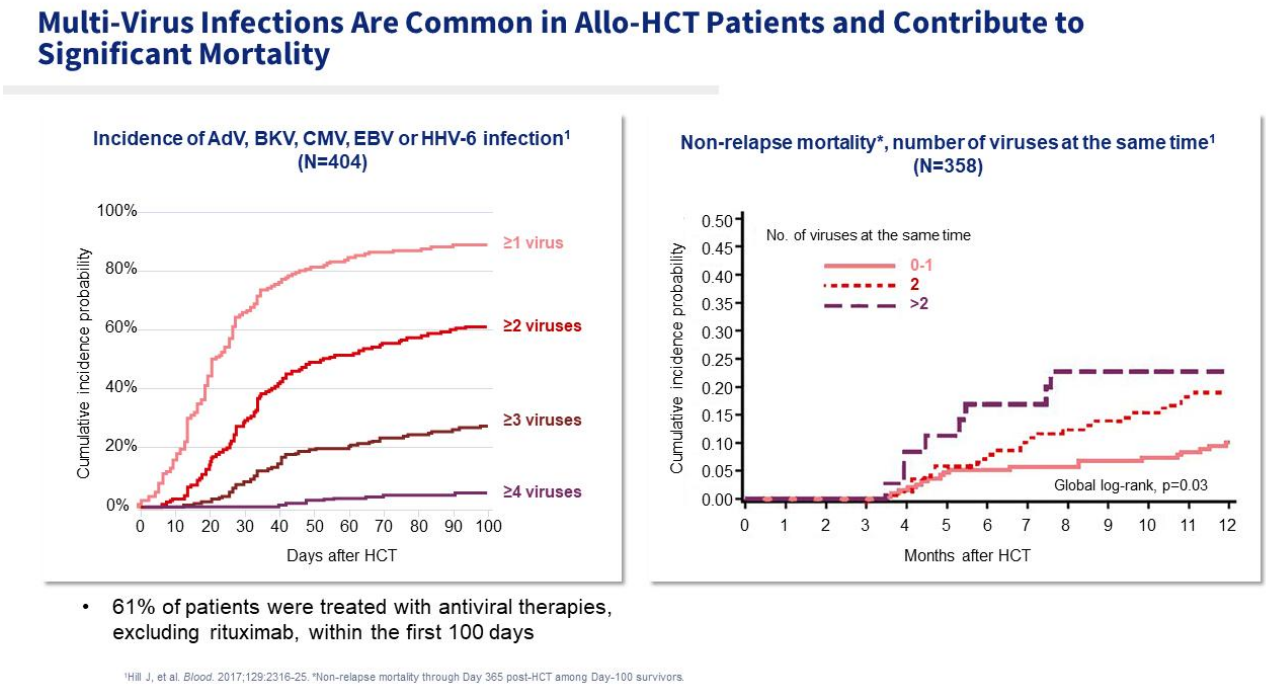

Figure 2. Approximately 90% of patients undergoing allogeneic HCT have at least one viral infection and 62% have more than one. Multiple viruses contribute to significant mortality

SOT has been established as a definitive treatment option for patients with organ failure. Over the past few decades, SOT procedures have rapidly progressed and now include a variety of solid organs, including the kidney, lung, liver, heart, intestine and pancreas. The increase in organ transplants has been matched by improved short- and long-term graft survival. This is due, in large part, to the use of immunosuppressive drugs that prevent the immune system from rejecting the transplanted organ. However, typically SOT patients require some degree of immunosuppressive therapy life-long, which leaves them vulnerable to viral infections and disease for a longer duration than HCT patients. In addition, high-risk SOT patients, including recipients of organs mismatched at a high number of HLA antigens, highly sensitized recipients, or ABO blood type incompatible recipients, tend to receive more rigorous immunosuppressive induction treatment, further increasing the risk of these patients contracting potentially deadly viral diseases. Further, SOT patients with the viral infections and diseases our product candidates aim to treat or prevent, suffer from worse outcomes, including graft failure, despite current standard of care treatment, as depicted in the figure below.

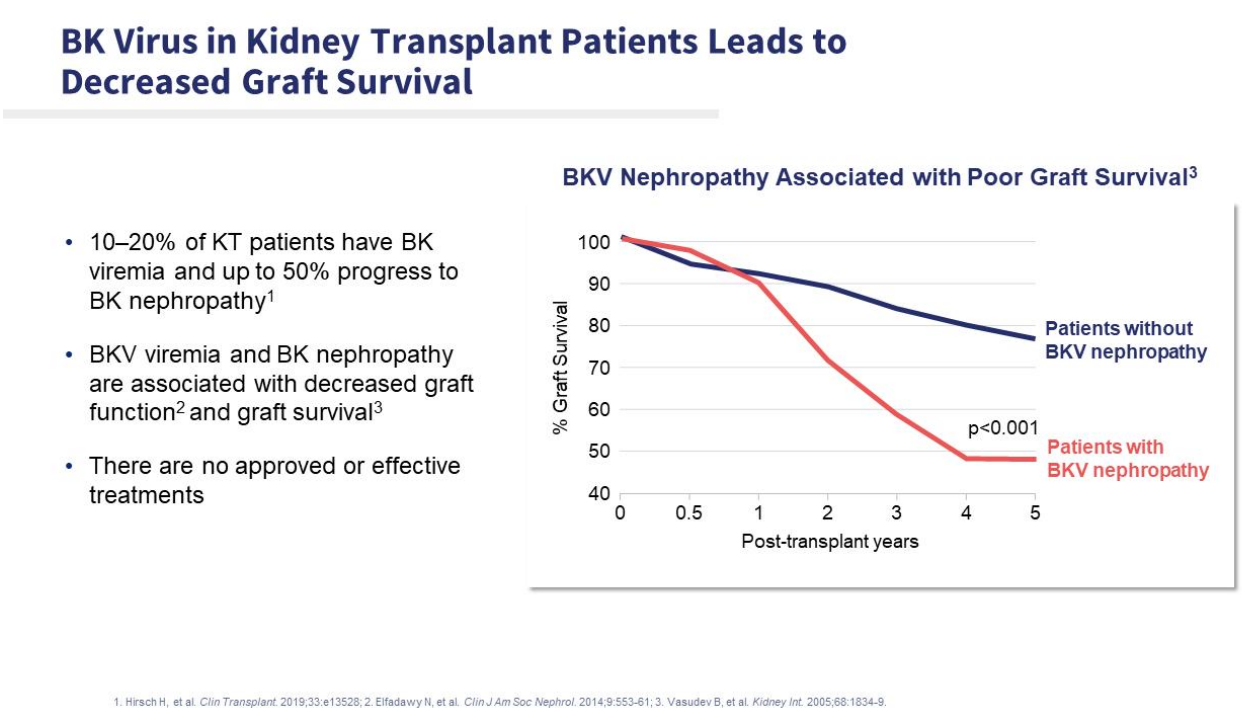

Figure 3. BKV in kidney transplant recipients leads to decreased graft survival despite standard of care

We believe transplant patients represent one segment of the large number of immunocompromised patients suffering from devastating viral infections who could potentially benefit from allogeneic, off-the-shelf VST therapies. Other individuals with weakened immune systems, including those with primary immunodeficiencies, the elderly and very young and patients who have compromised immune systems due to cancer or the treatment of their cancer are all at high risk of the life-threatening consequences of viral diseases and infections. Each of these target patient populations represents a large potential market that is currently untapped or underserved by existing therapies.

Limitations of Current Therapies for Immunocompromised Patients

There are no FDA- or EMA-approved antiviral drugs to treat the majority of the diseases and patients we are planning to target using our allogeneic off-the-shelf VSTs. When used clinically, available antivirals are often ineffective, toxic, can lead to emergence of virus escape mutants that are treatment-refractory and despite their use patients often succumb to their infections.

Similarly, there are limitations to prophylactic approaches, such as vaccines, in immunosuppressed patients, the elderly, and the very young who may be unable to mount an effective immune response that protects against the target viruses.

In contrast, the adoptive transfer of *ex vivo* expanded VSTs to HCT patients has generated promising preliminary disease outcome measures and safety data in treating a range of viral diseases in clinical trials. We designed an approach whereby VSTs could be prospectively generated from healthy, third-party donors expressing common HLA polymorphisms who were seropositive for all of the

targeted viruses. These VSTs were prepared by stimulating peripheral blood mononuclear cells, or PBMCs, with viral antigens followed by *ex vivo* expansion and cryopreservation to enable utilization when needed by patients. We then clinically assessed whether such allogeneic VSTs, when administered as a partially HLA-matched off-the-shelf therapy could still provide clinical benefit in a safe manner. We have treated more than 500 allogeneic HCT patients with either single or multi-virus targeted allogeneic VSTs. These off-the-shelf VSTs have been generally well-tolerated and were associated with clinical benefit as indicated by the high response rate demonstrated in immunocompromised patients with drug-refractory infections and diseases.

Our Approach to Allogeneic Off-the-Shelf T-Cell Immunotherapy

There is an urgent medical need for therapies to treat a large number of patients suffering from devastating viral diseases who currently have limited or no treatment options. Our approach involves the restoration of viral immunity through the adoptive transfer of VSTs, which have been prospectively generated from healthy, eligible donors. These cells are immediately available for "off-the-shelf" administration to patients at risk from the devastating consequences of viral diseases due to T-cell deficiencies, as depicted in the figure below. The partial HLA match between the allogeneic VST therapy and infected patient allows the infused T cells to recognize and selectively kill virus-infected cells while leaving non-virus-infected host cells intact, thereby minimizing the risk of therapy-associated graft-versus-host disease, or GVHD.

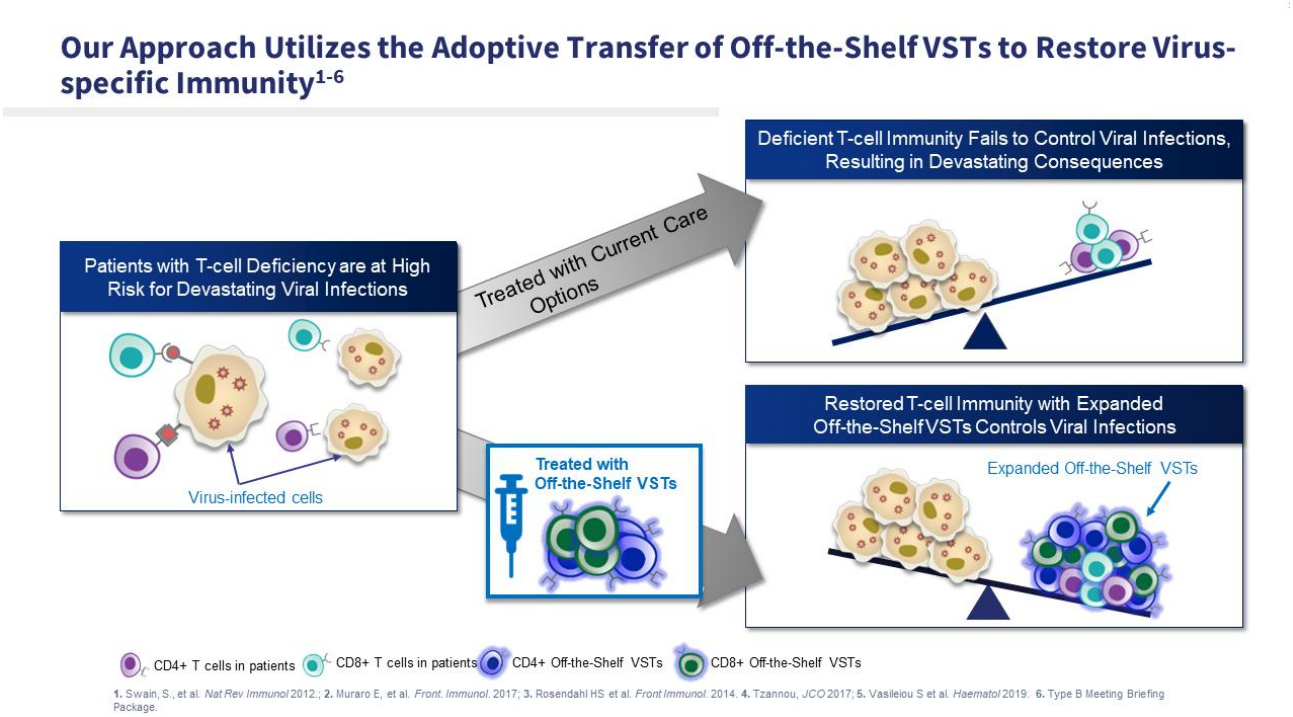

Figure 4. Adoptive transfer of off-the-shelf VSTs kill virus-infected cells and restore virus-specific T-cell immunity

Our VSTs are generated from a panel of healthy, third-party blood donors that collectively express a diverse array of HLA allele subtypes. Collectively, these VSTs, which therefore recognize viral peptides displayed by an array of different HLA alleles, form a mini-bank of product candidates that provide coverage to more than 95% of patients in our targeted populations. These VSTs can be stored in a cryopreserved state and thus supplied rapidly and globally as an off-the-shelf therapy for patients suffering from, or at risk for contracting, one or more viral diseases.

Using our versatile and robust off-the-shelf VST platform, we are able to rapidly generate VST therapies for the treatment of a spectrum of viral diseases. This is demonstrated by our pipeline of innovative, allogeneic off-the-shelf VST therapy candidates targeting both multi-virus (posoleucel and ALVR106) and single-virus indications (ALVR107).

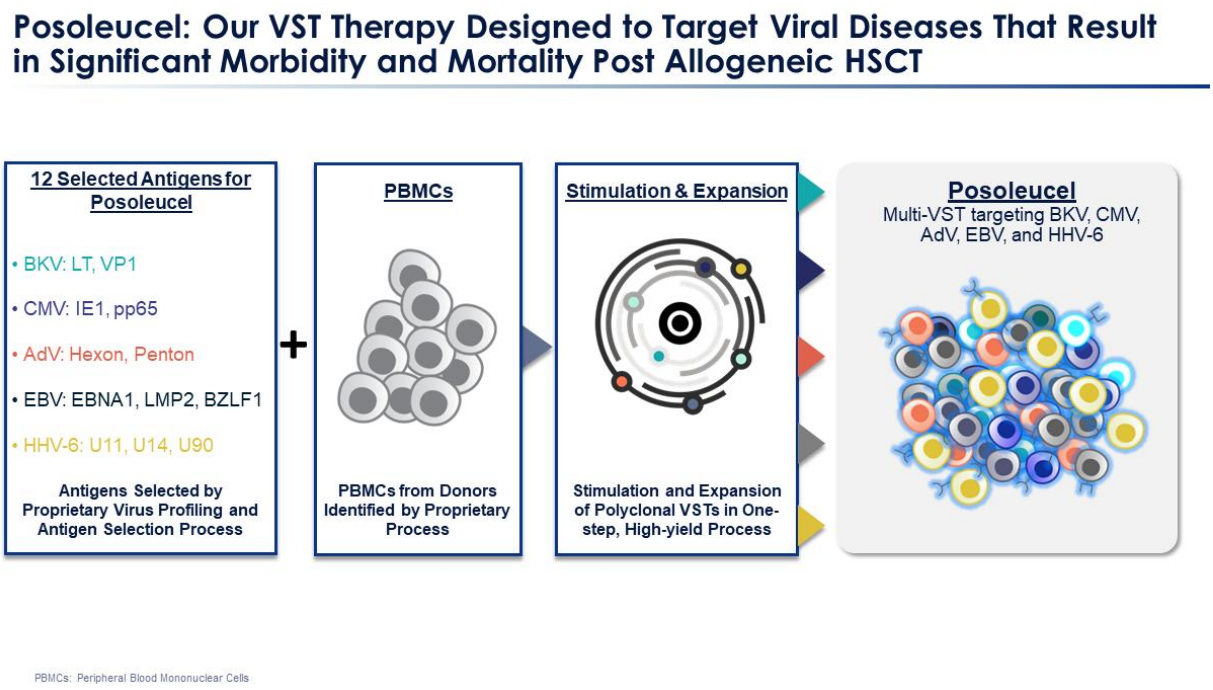

Figure 5. Schematic depicting how AlloVir's versatile off-the-shelf VST manufacturing platform is used to generate Posoleucel

Our Proprietary Allogeneic VST Therapy Process

We are uniquely positioned to rapidly develop and deploy T-cell therapies to treat and/or prevent a range of viral diseases, given our team's extensive experience in the fields of virology, immunology and cell therapy. We have leveraged this expertise to design the robust and reproducible allogeneic VST therapy production process depicted in the figure below. This process is comprised of three steps that enable the reliable generation of allogeneic, off-the-shelf, single or multi-virus-specific T cells: (1) our virus-specific T-cell profiling and targeted donor selection process, CytokinTM; (2) rapid and scalable off-the-shelf VST manufacturing; and (3) our proprietary, customized VST-cell line selection process, CytomatchTM, which allows for rapid patient access to our allogeneic VST therapy.

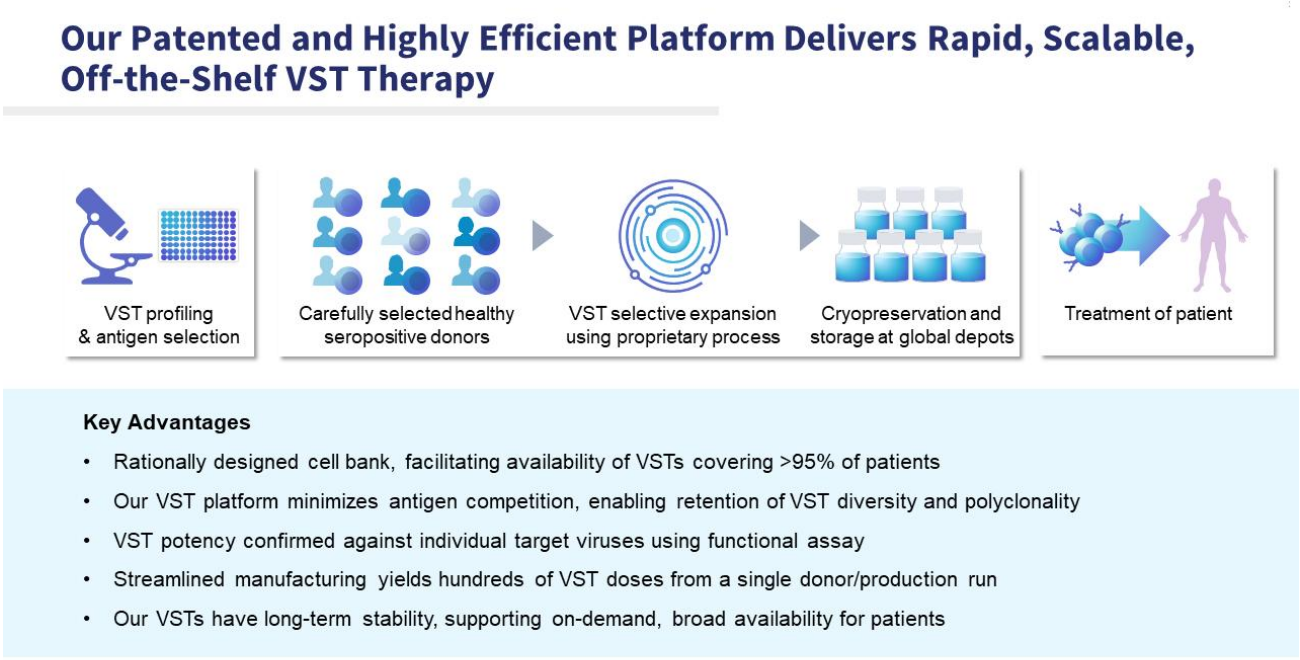

Figure 6. Key advantages of AlloVir's patented, highly efficient and industrialized VST platform

Step 1: Profiling T-Cell Responses to Viruses and Donor Selection

Identifying immunodominant viral antigens and selecting targeted donors, using Cytokin™, from whom to generate VSTs specific for these immunodominant viral antigens.

To define a hierarchy of immunodominance, we first analyze the T-cell immune response present in healthy individuals who have naturally controlled a viral infection. To delineate which viral antigens induce the strongest T-cell immune responses we evaluate two parameters: (1) the number of donors whose T cells recognize each of the expressed viral antigens and (2) the strength of the T-cell response induced by each antigen, as measured using functional assays such as production of cytokines. Using these parameters, we can establish a hierarchy of immunodominance and determine which antigens to select for incorporation into our VST manufacturing process. We identify and advance at least two viral antigens in each target virus. This allows us to generate polyclonal VSTs that recognize multiple parts of each of the target viruses, thereby minimizing the risk of virus immune escape with our product candidates.

***Donor Selection*—Cytokin™**

We next apply our Cytokin™ algorithm, as depicted in the figure below, to select the optimal combination of donors from whom to generate VSTs. Cytokin™ compares the HLA types of our targeted patient population with a pool of diverse healthy, eligible seropositive donors and identifies a subset of donors, or a mini-bank, that collectively provide greater than 95% of all patients with an appropriate partially HLA-matched VST line. To ensure redundancy and that each patient has multiple VST line options, we build one or more additional mini-banks using the same strategy. In this way, we can assure both breadth and depth of patient coverage with our VST bank.

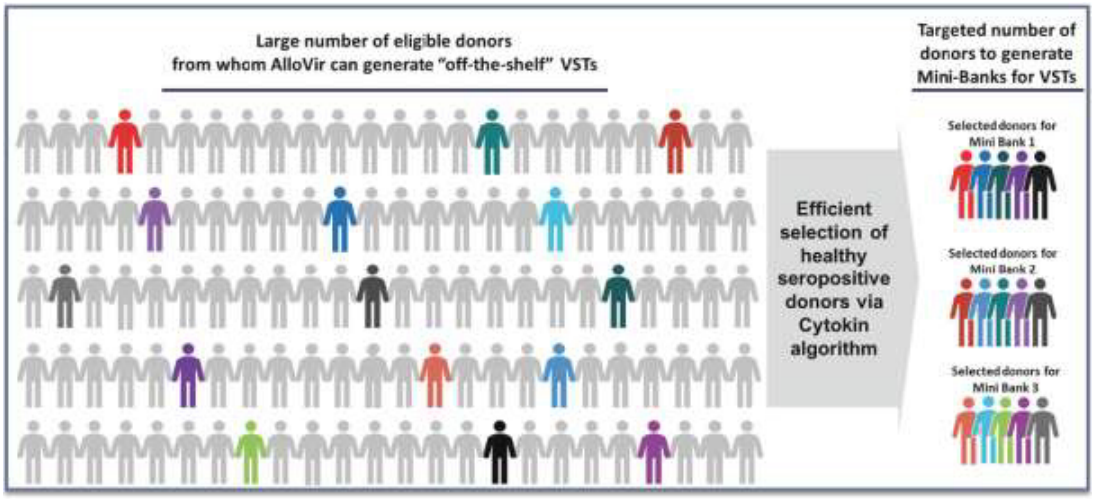

Figure 7. Implementing the Cytokin™ algorithm to efficiently select donors from whom to generate mini-banks of VSTs

Step 2: Rapid and Scalable Off-the-Shelf VST Manufacturing

Applying our patented manufacturing platform to selectively, efficiently and rapidly expand polyclonal VSTs that are cryopreserved and available as an off-the-shelf therapy

To selectively activate and expand VSTs, we stimulate donor peripheral blood mononuclear cells, or PBMCs, with overlapping peptide libraries spanning immunodominant viral target antigens, in cell culture medium supplemented with growth factors for a period of approximately two weeks. During this timeframe, polyclonal VSTs are stimulated and expand while T cells that could potentially react with non-virus-infected patient cells and cause toxicities such as GVHD are deselected. In addition, for each virus we target at least two viral antigens in order to minimize the risk of virus immune escape. Once generated, these VSTs are stably maintained in a cryopreserved state allowing for immediate patient access. Each manufacturing run from an individual donor yields hundreds of product candidate doses.

Our ability to generate allogeneic, off-the-shelf VSTs in a single expansion step allows us to minimize antigen competition and preserve polyclonality. As a result, our polyclonal VSTs are comprised of both helper (CD4+) and cytotoxic (CD8+) virus-specific T cells that recognize multiple parts of each of our target viral antigens, or viral peptides, presented by different HLA alleles. As a result, we can deliver our product candidate to patients based on partial HLA match. The partial HLA match between the allogeneic VST-cell line and infected patient allows the infused T cells to recognize and selectively kill virus-infected cells.

To facilitate investigational product supply for our clinical trials, we currently manufacture posoleucel and ALVR106 at external cGMP CMOs and leverage a network of cGLP contract testing laboratories. We are also able to leverage ElevateBio's cell therapy expertise to develop and manufacture VST therapies for clinical trials and commercialization. ElevateBio has established ElevateBio BaseCamp, Inc., or BaseCamp, a centralized cell and gene therapy development and manufacturing facility dedicated to the production of products for its affiliated companies. Therefore, we have also added ElevateBio BaseCamp to our manufacturing network.

Step 3: Cytomatch™ and Immediate Patient Access to Our Allogeneic VST Therapy

Rapidly identifying the appropriate VST line for each patient using the Cytomatch™ algorithm, ensuring immediate accessibility to therapy for high-risk patients

The final component of our process relates to the clinical use of our allogeneic off-the-shelf VST therapy. The Cytomatch™ algorithm guides the selection of the VST cell line for patient treatment. A specific drug product lot is selected for infusion based on the level of HLA matching between patient and associated VST-cell line, with two HLA allele matches set as a minimum threshold. The "best" VST-cell line is rapidly identified and can be immediately packed and shipped to the treatment center, where it can be thawed and infused to patients without the need for additional manipulation.

Our Highly Innovative Allogeneic VST Therapy Candidates

Our pipeline of allogeneic, off-the-shelf VST therapy candidates is designed to restore virus-specific T-cell immunity in patients suffering from, or at risk for, life-threatening viral diseases. Our proprietary VST therapy platform can be used to generate allogeneic cell therapies targeting single or multiple viruses at commercial scale. We own worldwide development and commercialization rights to all our cell therapies.

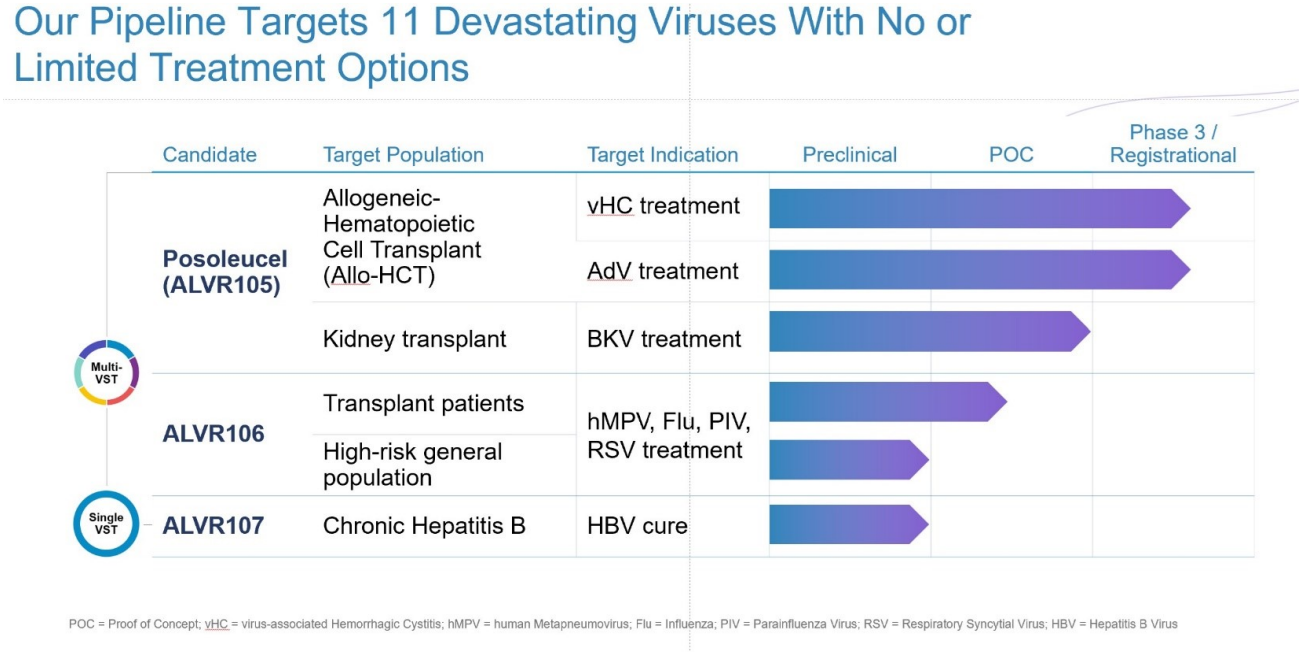

Figure 8. AlloVir's pipeline

Posoleucel

Our lead product candidate, posoleucel, is a multi-VST therapy targeting six viral pathogens: AdV, BKV, CMV, EBV, HHV-6 and JCV, which has the potential to fundamentally transform the treatment landscape for immunocompromised individuals.

Our initial focus was to develop posoleucel in immunocompromised HCT and SOT patients who are at high risk for life-threatening viral infections as follows:

- Treatment of virus-associated HC (BKV and/or AdV) in HCT patients

- Treatment of AdV infections in HCT patients
- Prevention of multi-virus infections (AdV, BKV, CMV, EBV, HHV-6 and JCV) in HCT patients
- Treatment of BKV infections in kidney transplant patients

Based on the strength of the posoleucel Phase 2 data for both treatment and prevention, the FDA has granted posoleucel Regenerative Medicine Advanced Therapy (RMAT) designation for three indications – for the treatment of HC caused by BKV, for the treatment of AdV infection in adults and children following allo-HCT, and for the prevention of clinically significant infections and disease caused by posoleucel's six target viruses. Similarly, based on data generated from the Phase 2 POC treatment trial and the critical medical need, the European Medicines Agency (EMA) has granted posoleucel PRIority Medicines (PRIME) designation for the treatment of serious infections with AdV, BKV, CMV, EBV and HHV-6. Posoleucel was one of the first seven investigational therapies to receive both PRIME and RMAT designations and, to our knowledge, is the only investigational therapy to receive three RMAT designations. While these designations may not lead to a faster development process and do not increase the likelihood that a product candidate will receive approval from the FDA or EMA, we expect that PRIME and RMAT designations will result in increased EMA and FDA interactions to support our development efforts and may enable an expedited regulatory review process. In addition, the FDA also granted posoleucel Orphan Drug Designation for the treatment of virus-associated HC, and the EMA granted Orphan Medicinal Product designation to posoleucel for its targeted viruses in HCT patients, including for the potential prevention of infections or disease by these viruses.

Posoleucel for Allogeneic HCT Patients

HCT conditioning regimens often require the complete elimination of a patient's own stem cells, a procedure referred to as myeloablation. These patients are left without a functioning immune system and are consequently in a severely immunocompromised state until their donor stem cells take hold, or engraft, and repopulate the bone marrow. During this period, these patients are highly susceptible to infection. We believe that, as depicted in the figure below, our VST therapy candidates can play the key role of providing bridging immunity between myeloablation, where patients have little-to-no immune function of their own, and reconstitution of their immune systems after the donor stem cells engraft and expand to physiologic levels. We believe that by restoring immunity during this time of severe immune compromise, our VST therapy candidates may substantially reduce or prevent virus-associated morbidity and mortality, thereby dramatically improving patient outcomes.

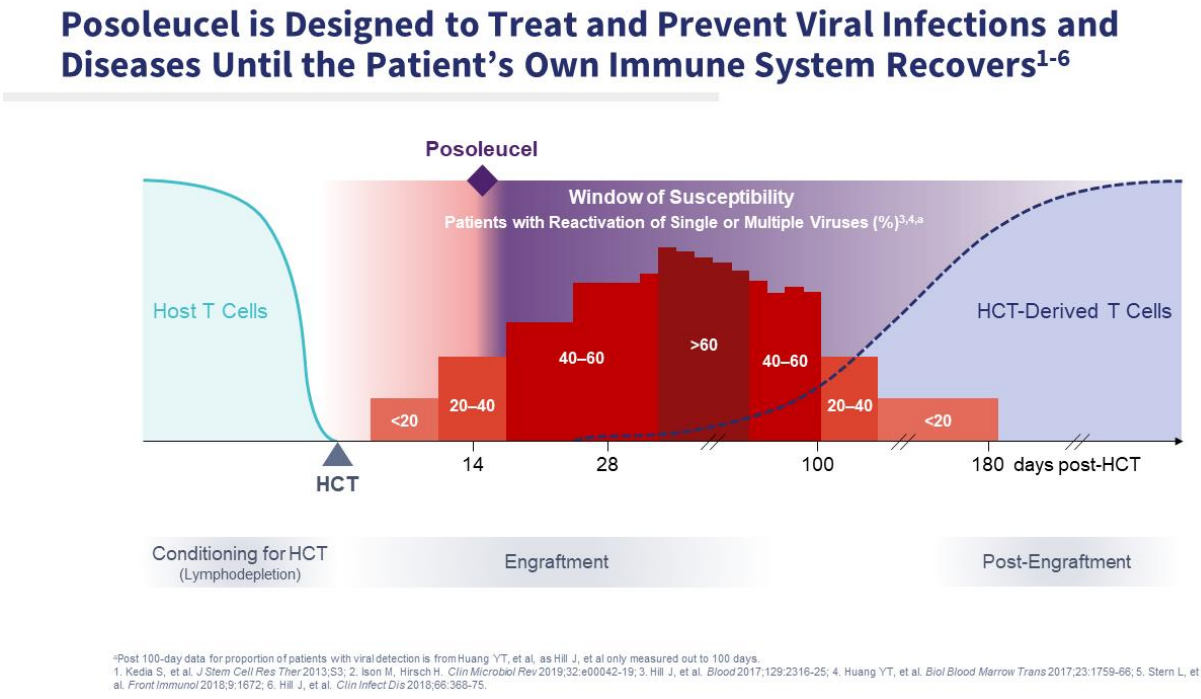

Figure 9. Posoleucel is designed to treat and prevent viral diseases until the patient's own immune system recovers

In approximately 90% of allogeneic HCT patients, the suppressed immune system allows viruses that were previously in a latent, quiescent state to reactivate. Furthermore, more than 60% of allogeneic HCT patients experience a reactivation of more than one virus targeted by posoleucel. These viral infections can cause multi-organ disease and multi-organ failure that may be life-threatening and that typically require hospitalization. It is estimated that more than 20% of all deaths associated with HCTs are due to infections. There are currently no FDA- or EMA-approved therapies for treating most viral infections in the post-transplant setting, and current antiviral therapies are associated with significant toxicity, including renal insufficiency and bone marrow suppression.

Posoleucel Phase 2 POC CHARMS Clinical Results in Allogeneic HCT Patients

We evaluated posoleucel in a Phase 2 open-label POC trial where VSTs were administered to 58 allogeneic HCT patients with treatment-refractory infections. We refer to this trial as CHARMS.

The primary objective of CHARMS, which was not statistically powered for superiority or significance, was to determine the feasibility and safety of administering partially HLA-matched multi-VST therapies targeting six viruses in HCT patients with persistent viral reactivations or infections. Patients were eligible following any type of allogeneic transplant if they had AdV, BKV, CMV, EBV, HHV-6 and/or JCV infections that were relapsed, reactivated or persistent despite standard antiviral therapy.

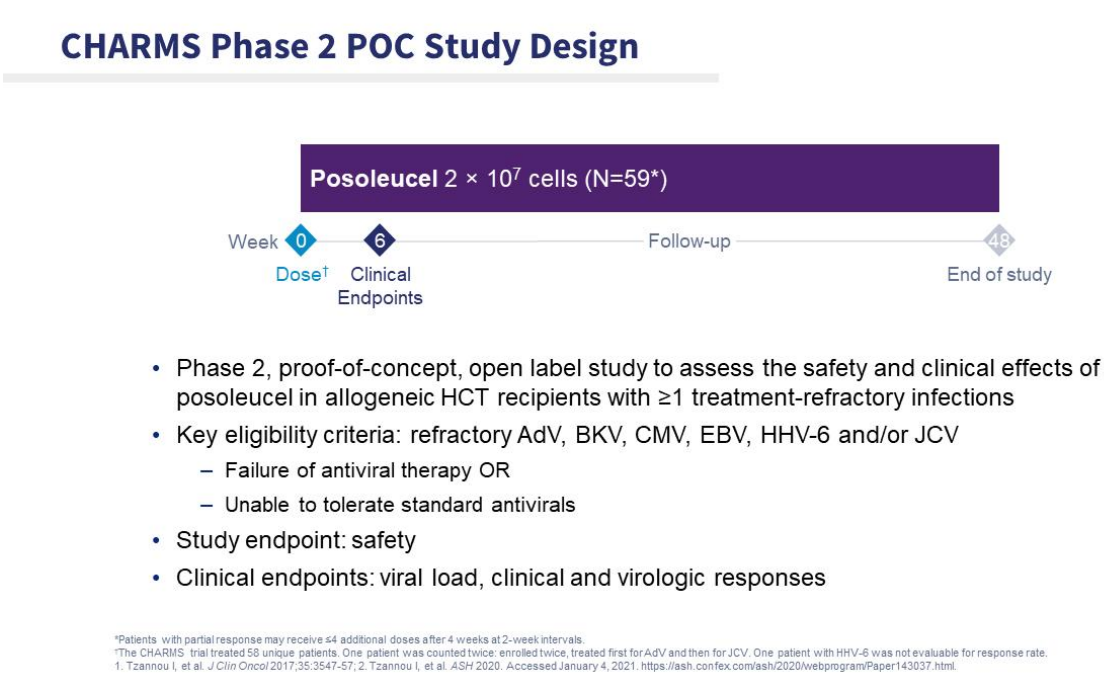

Figure 10. CHARMS—Phase 2, proof-of-concept, open-label trial design

The treatment schedule encompassed an initial single infusion of 2 x 10^7 partially HLA-matched multi-VSTs/m^2. If the patients had a partial response, or a PR, within 28 days of the first infusion, as defined by a 50% or greater fall in viral load, they were eligible to receive up to four additional doses from day 28 after the initial infusion and at two weekly intervals from day 28.

Efficacy endpoints for CHARMS were resolution of the target infections, as measured by viral load, and resolution of clinical signs and symptoms, as determined by the primary investigator. Clinical and virologic responses were assessed by week 6 per protocol and at additional timepoints where feasible. A complete response, or CR, was defined as return of viral load to normal range and resolution of clinical signs and symptoms. A PR was defined as a decrease in viral load of at least 50% from baseline or 50% improvement in clinical signs and symptoms. No response, or NR, was defined as either stable or progressive disease.

The demographics and clinical characteristics for the 58 unique patients enrolled and treated in the CHARMS trial are presented in Table 1. These patients were infused with posoleucel therapy matched at one to seven HLA alleles. In this clinical trial, we observed the delivery of partially HLA matched VSTs were generally well-tolerated. These final trial results were published in Clinical Cancer Research in January 2023.

Characteristic	Number (%)
Sex (N = 58)[a]	
Male	30 (52)
Female	28 (48)
Age (N = 58)[a]	
Pediatric (18 years of age)	18 (31)
Adult	40 (69)
Race (N = 58)[a]	
Black or African American	3 (5)
White	51 (88)
Asian	3 (5)
Evaluable infections treated (N = 70)	
BKV	27 (39)
CMV	24 (34)
AdV	12 (16)
HHV-6	4 (6)
EBV	2 (3)
JCV	1 (1)
Number of infections per patient at study entry (N = 58)[a]	
1	46 (79)
2	11 (19)
3	1 (2)
Number of infusions per patient (N = 58)[a]	
1	44 (74.6)
2	11 (18.6)
3	4 (6.8)

[a] The CHARMS trial treated 58 unique patients. One patient was enrolled twice, treated first for AdV and then for JCV. This patient was counted twice for some efficacy and once for safety. One patient with HHV-6 was not evaluable for response rate.

Table 1. CHARMS clinical trial patient demographic and clinical characteristics

Clinical and Virologic Response

Of the 58 unique patients evaluated for efficacy by six weeks post infusion, 55 had a CR or PR, representing a 95% response rate, as depicted in the figure below. Twelve patients were co-infected with at least two different viruses and of these, ten patients (83%) responded to posoleucel by six weeks post-infusion. This demonstrates the potential for treating patients with multiple viral infections with off-the-shelf posoleucel.

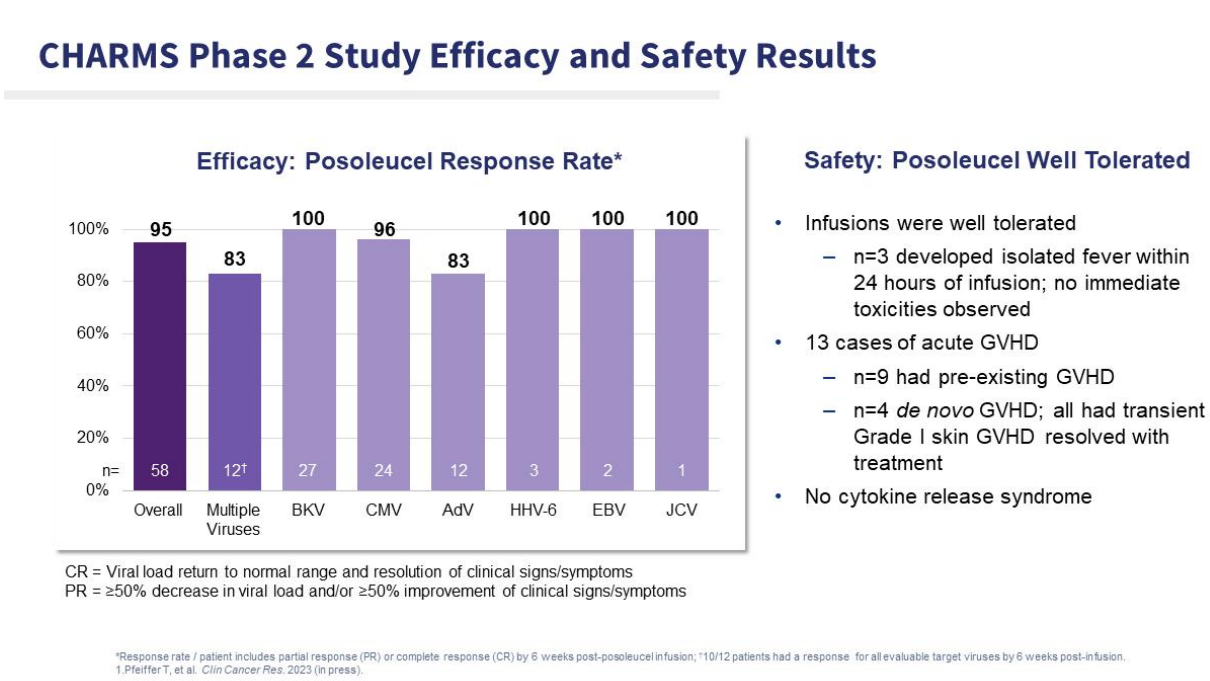

Figure 11. Posoleucel Phase 2 proof-of-concept trial (CHARMS): 95% overall response rate in patients with viral disease by 6 weeks in 58 unique patients

In Vivo VST Persistence

In order to provide bridging immunity to HCT patients, allogeneic off-the-shelf VSTs must persist and provide continued antiviral protection until the transplanted stem cells engraft and the patient's own immune function is restored. To examine how long our posoleucel cells persisted in patients, we examined the peptide epitope specificity of circulating T cells to discriminate between infused and endogenous virus-specific T cells. Of 16 patients that we tested, we were able to confirm the persistence of allogeneic VSTs in 11 patients for up to 12 weeks.

Safety Profile

The overall analysis of preliminary safety results gathered in the CHARMS trial showed that treatment with posoleucel was generally well-tolerated.

Safety monitoring in the CHARMS trial consisted of several assessments, including assessments of both GVHD and serious adverse events, or SAEs, as reflected in the table below. Overall, 23 deaths occurred during the study; none of these deaths was deemed related to study treatment. Of the 23 deaths, 6 were associated with treatment-emergent AEs (TEAEs), and 5 deaths occurred during the protocol-specified AE reporting period. Treatment-related TEAEs ≥ Grade 3 occurred in 8 (13.8%) participants, however there were no TEAEs leading to interruption or discontinuation of study intervention, there were no dose-limiting toxicities, and no deaths were attributed to treatment-related TEAEs.

In general, safety findings were consistent with those expected in an allogeneic HCT patient population with persistent and/or refractory viral infections, including the known risks of GVHD. To date, no overt safety signal has been detected above and beyond the safety findings expected to be found in patients who have already undergone allogeneic HCT.

13 patients with acute GVHD (within 42 days of last infusion of posoleucel)	<u>9 patients with prior history of acute GVHD</u> • 5 grade I and 1 grade II skin GVHD: resolved or improved with topical treatment • 1 grade I skin GVHD: resolved after systemic corticosteroids • 1 grade II skin GVHD flare: resolved after resumption of systemic corticosteroids • 1 grade III GI GVHD flare: occurred coincident with rapid corticosteroid taper, resolved after resumption of systemic corticosteroids <u>4 patients with *de novo* GVHD</u> • 2 grade I skin GVHD: resolved with topical treatment • 1 grade I skin GVHD: resolved with tacrolimus and prednisone • 1 grade I skin GVHD: resolved with topical treatments plus low-dose systemic corticosteroids
6 grade 5 SAEs (deaths)	• 3 multi-organ failure • 1 respiratory failure • 2 deaths not otherwise specified
8 grade 4 SAEs (reported from 7 patients, 5 of whom also had Grade 5 SAEs reported and are included above)	• 2 respiratory failure • 2 aspartate aminotransferase increased • 1 hypoxia • 1 dyspnea • 1 sepsis • 1 vomiting

Table 2. Serious adverse events and GVHD in the CHARMS trial

Treatment of Virus-Associated Hemorrhagic Cystitis

HC is the primary clinical manifestation associated with BKV following HCT, occurring in 8-25% and 7-54% of pediatric and adult patients, respectively. HC can also be caused by other viruses, including AdV and CMV. However, up to 90% of cases of HC are caused by BKV.

Between 65-90% of individuals are infected with BKV by the age of ten. Most infections are asymptomatic, but the virus remains latent in the body, primarily in kidney cells throughout life. BKV can reactivate during periods of immune compromise with the virus being detected in the urine of over half of HCT patients.

More than half of patients with HC present with clot formation and/or severe bladder hemorrhage with renal impairment. Bleeding may be life-threatening requiring urologic interventions including the removal of the urinary bladder, or cystectomy. Clinical manifestations of HC include kidney dysfunction or failure, bright red-colored urine due to the presence of blood in the urine, as well as abdominal pain so severe and debilitating that patients often require continuous narcotic infusions.

A recent, prospective, multi-center trial of the natural history of BKV after allogeneic HCT in 193 patients found that:

- 22% of patients developed grade 2 or higher HC, and 18% had a high level of BK viremia (10,000 copies/mL) in the first three months post-HCT;
- Patients with a high level of BK viremia in the first three months after transplant had a significantly lower estimated glomerular filtration rate, or eGFR, at 12 and 24 months (on average 20mL/min/m^2 lower by two years after transplant) and a 6-fold higher risk of receiving dialysis (p=0.004);
- Patients with high levels of BK viremia have been found to have significant reduction in kidney function (17-26% below baseline) as compared to patients with low levels of BK viremia (4-5% below baseline). Additionally, 18% of patients with high levels of BK viremia required dialysis, compared with 3% of patients with low levels of BK viremia;
- A high level of BK viremia was associated with a significantly higher risk of death;
- Virus-associated HC has been associated with increased mortality, with patients with high levels of BK viremia experiencing mortality rates of 44%, compared with 19% in patients with low levels of BK viremia;

- Asymptomatic viremia was common and associated with decreased kidney function, and;
- Patients with detectable BKV-specific T cells were 5-fold more likely to clear viremia, but patients who received off-label cidofovir were not.

There are currently no FDA- or EMA-approved therapies for virus-associated HC. The current standard of care relies on supportive care to address the symptoms and manifestations of HC; urinary bladder irrigation to avoid its obstruction by blood clots; narcotics to alleviate suffering; hyperbaric oxygen therapy; cystectomy in uncontrollable bleeding cases; and dialysis for acute renal failure. The antiviral cidofovir is sometimes used off-label to treat virus-associated HC. However, cidofovir has been associated with kidney toxicity, which may compound the kidney damage caused by virus-associated HC itself.

Posoleucel Clinical Data—BKV

In our Phase 2 proof-of-concept trial for posoleucel, we treated 27 evaluable patients with BKV disease and 100% achieved an overall response by six weeks post-infusion. Overall response rates were defined as achieving either a PR or CR by six weeks post-infusion, as described in the protocol criteria.

In 23 patients infused with posoleucel, HC severity was retrospectively graded using the National Cancer Institute cystitis grading scale. This was performed by three physicians independently based on chart review of clinical and laboratory documentation. These patients treated with posoleucel therapy showed a rapid improvement in disease severity; complete resolution of macroscopic hematuria was observed in 43%, 61% and 74% of patients weeks 2, 4 and 6 post-infusion.

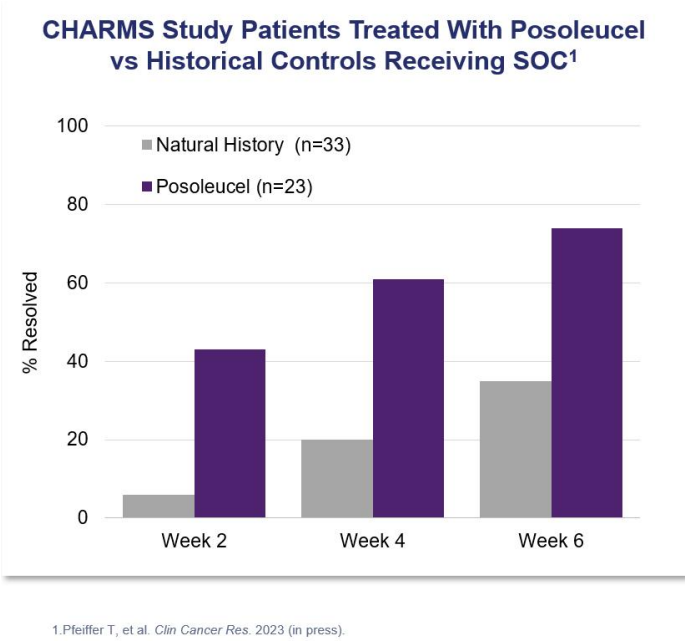

Figure 12. Time to resolution of BKV-HC following treatment with posoleucel

In a retrospective study conducted at BCM, out of 33 pediatric allogeneic HCT patients with an average of Grade 3 BK-HC receiving current standard of care, only 36% had resolved their disease by week 6. Furthermore, less than 10% of the patients had resolved their disease by week 2.

We believe our data provide preliminary evidence demonstrating that posoleucel has the potential to meet unmet medical needs in allogeneic HCT patients with virus-associated HC.

Clinical Development Plan

We initiated a multicenter, randomized, double-blind, placebo-controlled Phase 3 trial to assess the safety and efficacy of posoleucel therapy compared to placebo for the treatment of patients with virus-associated HC following allogeneic HCT. The primary

endpoint was the time to resolution of macroscopic hematuria. As these HCT patients often experience multiple viral infections, secondary endpoints included the reduction in viral load for AdV, CMV, EBV, HHV-6 and JCV.

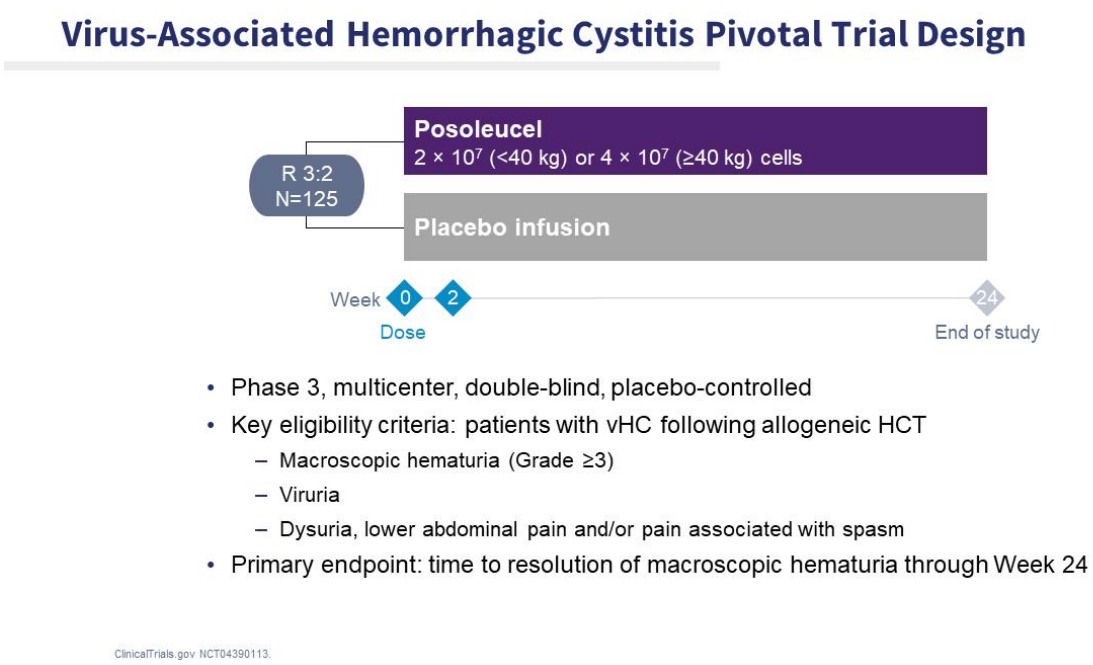

Figure 13. Phase 3, multicenter, randomized, double-blind, placebo-controlled virus-associated HC trial design

In December 2023 the DSMB monitoring the trial met and recommended stopping the trial due futility because the interim data reviewed suggested the trial was unlikely to meet its primary endpoint. As such, we discontinued the trial and have stopped all clinical development of posoleucel for the treatment of virus-associated HC.

Treatment of Adenovirus Infections

AdV viremia occurs in 32% of pediatric allogeneic HCT patients and 6% of adult allogeneic HCT patients. In the HCT setting, patients can present with AdV disease due either to reactivation or de novo exposure. Infection usually occurs between two and three months post-transplant and is a significant cause of morbidity and mortality. The spectrum of AdV-associated disease in HCT patients ranges from mild gastroenteric or respiratory symptoms to severe hemorrhagic enteritis, hemorrhagic cystitis, nephritis, hepatitis, pneumonia, encephalitis, myocarditis, and potentially lethal multiple organ involvement, frequently associated with hepatic failure. Off-label use of cidofovir has been established as the current standard of care treatment to control the replication of virus and prevent disseminated viremia. However, it has limited efficacy irrespective of dose and its use is limited due to toxicity to the kidneys and poor bioavailability. To date, no adequately powered, randomized well-controlled trials demonstrating significant efficacy of cidofovir use for adenoviral disease versus control have been performed.

Posoleucel Clinical Data—AdV

In our CHARMS trial, 83% of patients with AdV infection achieved a response by six weeks post-infusion.

Clinical Development Plan

We initiated a multicenter, randomized, double-blind, placebo-controlled Phase 3 trial to assess the safety and efficacy of posoleucel therapy for the treatment of pediatric and adult allogeneic HCT patients with AdV infection at the end of 2021.

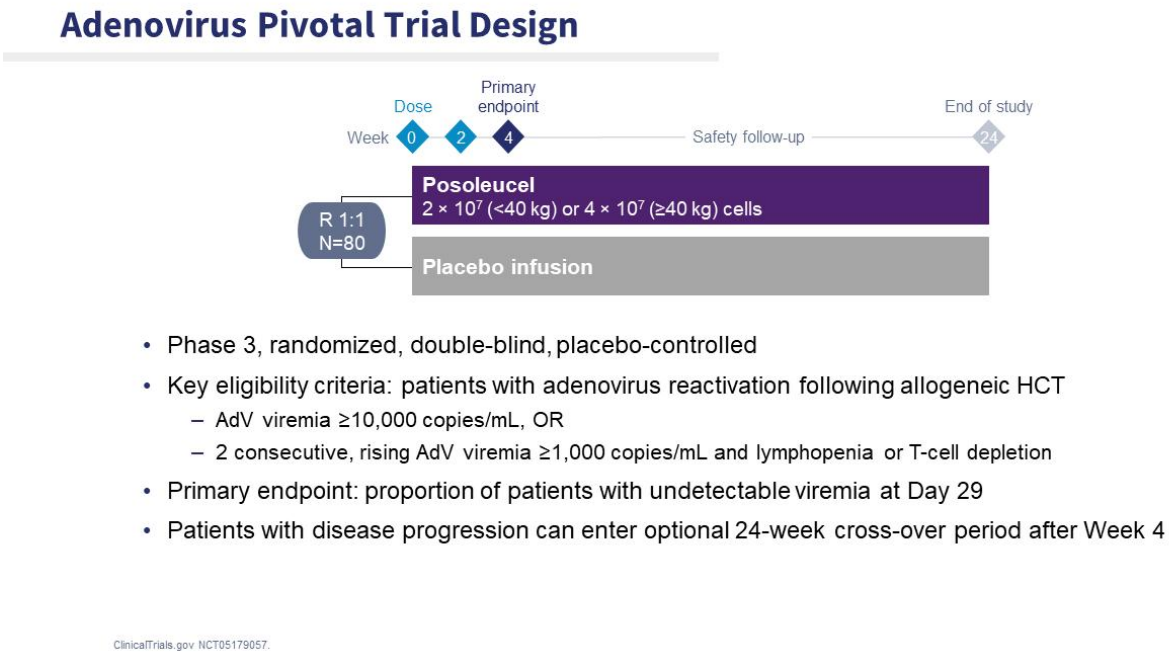

Figure 14. Phase 3, randomized, double-blind, placebo-controlled adenovirus treatment trial design

In December 2023, the DSMB monitoring the trial met and recommended stopping the trial due futility because the interim data reviewed suggested the trial was unlikely to meet its primary endpoint. As such, we discontinued the trial and have stopped all clinical development of posoleucel for the treatment of AdV.

Prevention of Multi-Virus Infection and Associated Disease in HCT Patients

Approximately 90% of all allogeneic HCT patients experience at least one infection associated with BKV, CMV, AdV, EBV or HHV-6 and more than 60% of patients experience infections caused by two or more of these five viruses within 100 days post-allogeneic HCT. Because of the increased morbidity and mortality associated with viral infections in transplant patients, prevention of viral disease is important for the overall health and survival of patients. Prophylactic therapy, which is a treatment administered to patients at risk for developing viral disease, and preemptive therapy, a treatment of patients with evidence of virus replication in blood, are the two major strategies used for disease prevention. Clinical guidelines recommend that allogeneic HCT patients infected with CMV or AdV should be monitored weekly for virus replication with a sensitive diagnostic technique for at least the first three months after HCT. There are currently no FDA- or EMA-approved antiviral therapies for prevention of multiple viral diseases or infections in transplant patients with one single therapy. For CMV alone, letermovir is approved for CMV in seropositive patients. However, drug resistant CMV has emerged with the use of letermovir, which may limit or restrict its utility.

Posoleucel Clinical Data—Multi-Virus Prevention in HCT Patients

Out of 26 high-risk allo-HCT patients who received posoleucel in this open-label study, 22 (85%) patients experienced reactivation of at least one of posoleucel's target viruses. Despite these expected high rates of viral reactivation, only three clinically significant infections were observed through Week 14. These results represent a substantial reduction in the expected rate of clinically significant viral infections or diseases in this high-risk patient population. Biomarker analyses demonstrated that viral control was associated with expansion of functional VSTs, and the presence of posoleucel was confirmed both during the infusion period and up to 14 weeks after

the last infusion.

Treatment with up to seven doses of posoleucel over 12 weeks was generally well tolerated with no unanticipated safety signals. Rates of GVHD were similar in frequency and severity to those expected in this high-risk allo-HCT population. Three (12%) treatment-related serious adverse events were reported. No episodes of cytokine release syndrome were reported.

Clinical Development Plan

Based on preliminary data from the open-label, Phase 2 POC study for multi-virus prevention, we initiated a global, registrational Phase 3 multicenter, randomized, double-blind, placebo-controlled clinical trial of posoleucel for multi-virus prevention.

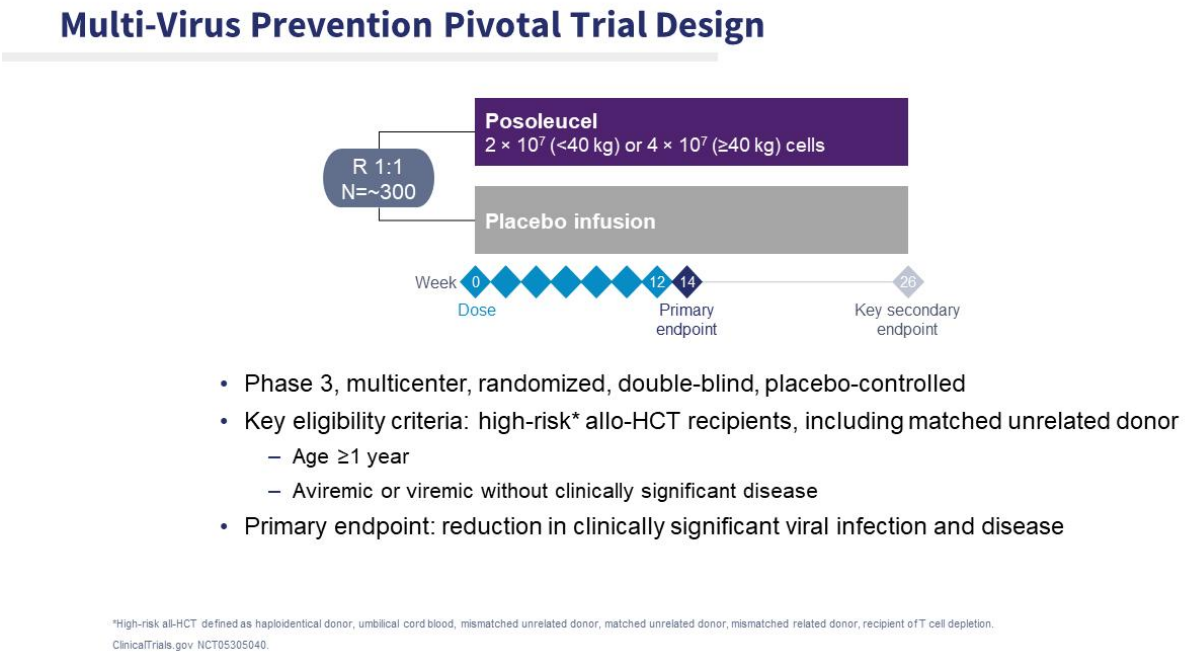

Figure 15. Phase 3, randomized, double-blind, placebo-controlled multi-virus prevention trial design

In December 2023, the DSMB monitoring the trial met and recommended stopping the trial due futility because the interim data reviewed suggested the trial was unlikely to meet its primary endpoint of the number of clinically significant infections or episodes of end organ disease through week 14. As such, we discontinued the trial and have stopped all clinical development of posoleucel for the prevention of viral infection and disease.

Treatment of BKV Infections in Kidney Transplant Patients

BK virus reactivation in KT patients is due to T-cell immune deficiencies caused by intensive immunosuppressive induction therapy followed by maintenance immunosuppressive treatment. BKV reactivation causes interstitial nephritis and progressive allograft injury. Routine screening for BKV reactivation after transplantation has been widely recommended and is performed at most transplant centers. The goal of diagnosing and managing BK viremia early in the course of active infection is to prevent allograft failure that is associated with BKV-associated nephropathy. BK viremia is detected in up to 20% of KT patients and up to 50% of patients with BK viremia progresses to BK nephropathy, resulting in decreased graft function and graft survival. Nearly half of all patients who develop BK nephropathy experience allograft failure. Because KT patients remain on immunosuppression for life, BK viremia and BK nephropathy onset is not restricted to the first year post-transplant. There are currently no FDA- or EMA-approved therapies for the treatment of BK viremia or BK nephropathy in KT patients. Treatment primarily involves reduction of immunosuppression. However, this results in patients being at increased risk of immune mediated acute allograft rejection.

Posoleucel Clinical Data— BKV Treatment in Kidney Transplant Patients

In February 2023, we announced positive data from a proof-of-concept, multi-center, randomized, double-blind, placebo-controlled, Phase 2 trial evaluating posoleucel for the treatment of BKV in KT patients.

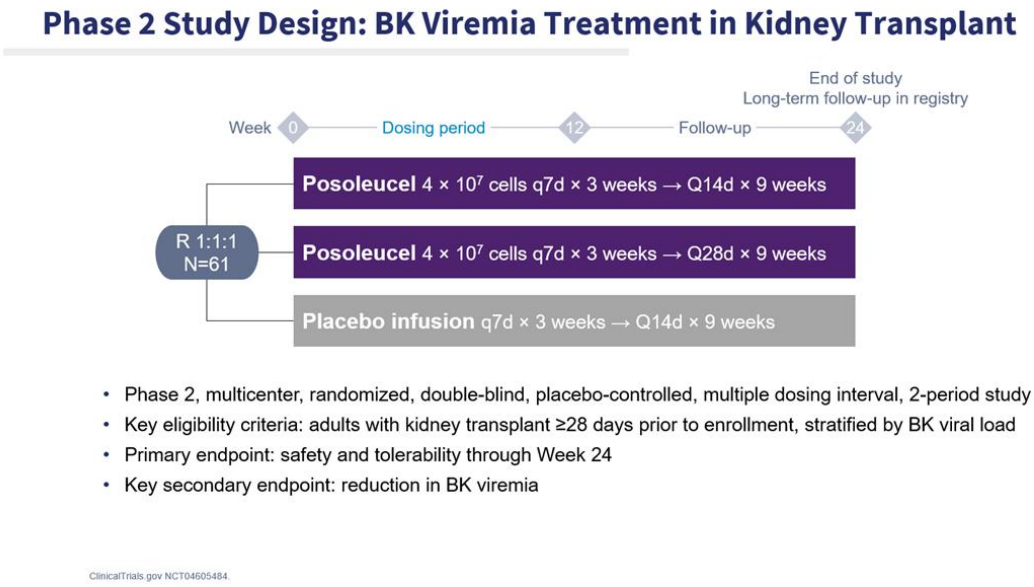

Figure 16. Phase 2, randomized, double-blind, placebo-controlled BK virus treatment in kidney transplant trial design

The primary endpoint of the posoleucel Phase 2 BKV treatment study in kidney transplant patients with BK viremia was the safety and tolerability of posoleucel versus placebo. Posoleucel was generally well tolerated in the study, with balanced safety across posoleucel dosing groups and placebo, and adverse events rates and severity consistent with the underlying patient population and background immunosuppression. Low rates of infusion reactions were observed in patients receiving posoleucel (2%) and those receiving placebo (5%). There were no deaths or reports of graft versus host disease or cytokine release syndrome. Emergence of donor-specific antibodies was uncommon and occurred with similar frequency in patients receiving posoleucel (7%) or placebo (5%). Three patients who received posoleucel were reported to have acute rejection per biopsy report by a central reader; none of these cases were assessed by the investigator as related to study drug.

The key secondary endpoint of the study was the change in BK viral load in patients receiving posoleucel versus those receiving placebo. The efficacy analysis excluded six patients in whom significant reductions in immunosuppression were made immediately prior to study entry. Posoleucel achieved greater viral load reductions versus placebo across all BK viral load measures. Antiviral responses among posoleucel patients increased over time, with maximal responses observed at Week 24. This clinically meaningful treatment effect was strongest among patients receiving posoleucel every two weeks and among those with high viral loads at study screening.

Clinical Development Plan

The topline data described above will inform next steps for this potential indication as well as a broader strategy in solid organ transplant patients.

Prevention of Multi-Virus Infection and Associated Disease in SOT Patients

Similar to HCT patients, the prevention of viral disease in SOT patients is important for both graft survival and the overall health and survival of patients. Published clinical guidelines recommend that all high and intermediate risk SOT patients, which account for nearly 90% of all SOT patients, should receive prophylactic therapy for CMV, which is only one of six viruses that posoleucel targets.

There are currently no FDA- or EMA-approved antiviral therapies for prevention of multiple viral diseases or infections in SOT patients with one single therapy. Learnings from our discontinued multi-virus prevention study in allogeneic HCT patients and our Phase 2 study of kidney transplant patients with BK viremia will inform the potential for a POC study of posoleucel for multi-virus prevention in SOT patients.

Other Viruses Targeted by Posoleucel

Epstein-Barr Virus

Epstein-Barr virus is a latent herpesvirus that infects more than 90% of humans worldwide and establishes life-long latency after primary infection. During a primary infection, an immunocompetent host will mount vigorous $CD4^+$ and $CD8^+$ cellular immune responses and these T cells control both the primary infection and any periodic EBV reactivations. However, EBV reactivation can cause significant morbidity and mortality in immunocompromised patients and uncontrolled EBV reactivation can lead to fulminant viremia and progress to life-threatening post-transplantation lymphoproliferative disorder, or PTLD.

PTLD can occur at any age and after all types of transplants, though allogeneic HCT patients are at particular risk. The median time to development of EBV-associated PTLD, or EBV-PTLD, after HCT is two to four months. Fever and lymphadenopathy are the most common symptoms and signs of EBV-PTLD and, if not treated, PTLD generally progresses rapidly to multi-organ failure and death. Off-label rituximab has been used to treat EBV-PTLD. However, response to rituximab is not universal and mortality remains high in rituximab-refractory patients. In December 2022, tabelecleucel received marketing authorization in Europe to treat patients with relapsed or refractory EBV-PTLD who have received at least one prior therapy; the cell therapy has not been approved in other regions at this time.

In our CHARMS trial, two evaluable patients with EBV infections were treated with posoleucel; the overall response rate to EBV by six weeks post-infusion was 100%.

Human Herpesvirus Type 6

There are two variants of HHV-6: HHV-6A and HHV-6B, both infect and establish latency in different cell types including CD4+ T lymphocytes, monocytes, and other epithelial, fibroblastic and neuronal cells. No disease has been causally linked to HHV-6A, and its natural history is unknown. In contrast, HHV-6B primary infection is ubiquitous in the first two years of life, sometimes causing *exanthema subitum* (also known as *roseola infantum* and sixth disease). Subsequent viral latency gives the potential for reactivation and disease.

HHV-6 reactivation is the most frequent cause of encephalitis after HCT. Disease onset is typically two to six weeks post-transplant. Initial signs and symptoms include confusion, delirium, short-term memory loss, syndrome of inappropriate antidiuretic hormone secretion and seizures. Long-term outcomes can result in brain damage, memory defects and death. HHV-6 is also associated with delayed engraftment, allograft failure, acute GVHD and CMV reactivation. There are currently no FDA-approved treatments for HHV-6. The use of off-label antivirals is limited by several factors. Ganciclovir is associated with dose-limiting bone marrow toxicity which may delay HCT engraftment, cidofovir is associated with kidney toxicity and foscarnet is also associated with kidney toxicity, as well as the risks of infection and deep vein clots stemming from its required route of administration.

In our CHARMS trial, three evaluable patients with HHV-6 infections were treated with posoleucel; the overall response rate by six weeks post-infusion was 100% (3/3). One additional patient was found to have chromosomal integration of HHV-6 and was excluded from the efficacy analyses.

ALVR106: VST Therapy for the Treatment of Patients with Respiratory Viruses

Acute respiratory tract infections due to respiratory viruses including RSV, influenza, PIV, hMPV and coronaviruses such as SARS-CoV-2, the virus that causes COVID-19, are a major public health concern. For example, RSV-induced bronchiolitis is the most common reason for hospital admission in children less than one year of age. The lack of approved antiviral agents to treat many respiratory viruses underscores the need for alternative treatment and prevention strategies.

ALVR106 is an allogeneic, off-the-shelf VST therapy designed to treat or prevent four common respiratory viruses, RSV, influenza, PIV, and hMPV. A Phase 1/2 proof of concept clinical trial of ALVR106 to target severe respiratory diseases in high-risk populations was initiated in 2022. Part A of the trial has now completed enrollment, but we have discontinued this trial pending the outcome of our review of strategic alternatives.

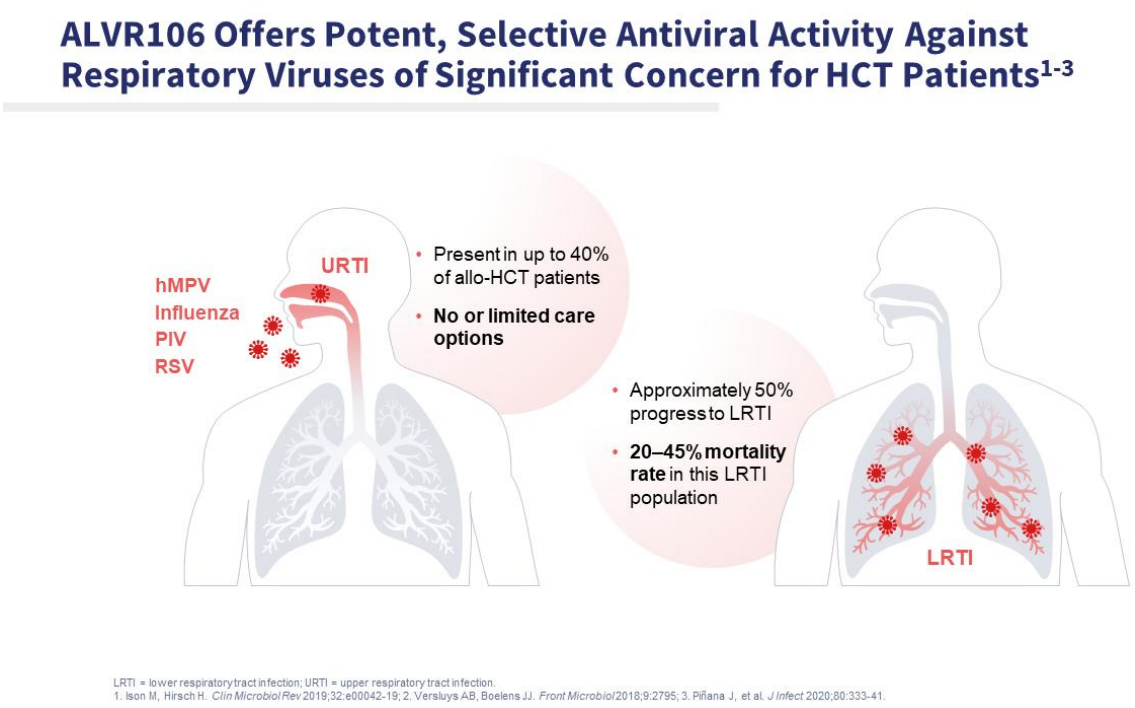

Figure 17. Consequences to high-risk patients with respiratory virus infections

Preclinical Data

As illustrated below, our preclinical *in vitro* data demonstrates that ALVR106 can be reproducibly generated from healthy seropositive donors and reactive cells have potent antiviral activity against each of the target viruses. Additionally, these cells do not target non-virus-infected autologous or allogeneic cells. We believe this data supports the potential for antiviral benefit and safety of ALVR106 when administered to patients.

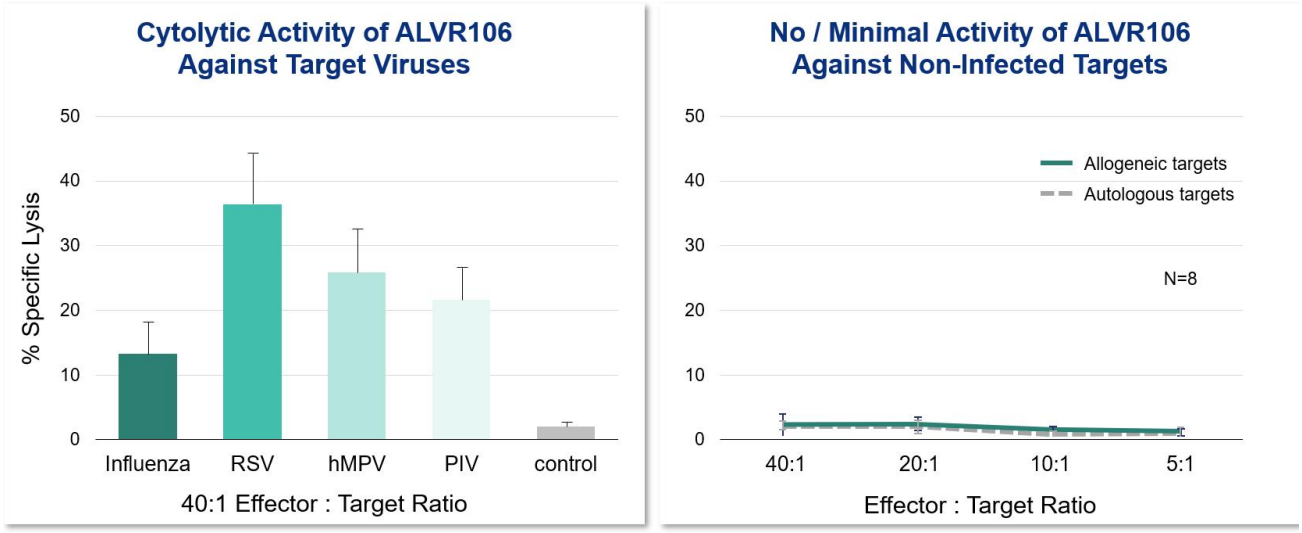

Figure 18. ALVR106 has selective antiviral activity against target viruses, leaving non-virus infected targets intact

Respiratory Virus Infections in HCT Patients

Respiratory tract infections due to RSV, influenza, PIV and hMPV, are detected in up to 40% of allogeneic HCT patients. In approximately half of these patients, these viral infections progress from less serious upper respiratory tract infections, with symptoms similar to those of a common cold, to far more serious lower respiratory tract infections, with severe symptoms including pneumonia and bronchiolitis. These more serious infections are associated with mortality rates between 20-45%.

RSV

RSV is a common infectious complication of transplantation, with an incidence of up to 12% in HCT patients. In immunocompetent adults, infections from RSV typically result in upper respiratory tract infections characterized by cough, fever and runny nose. However, in approximately two-thirds of infected HCT patients, an RSV infection develops into a lower respiratory tract infection characterized by severe symptoms including pneumonia and bronchiolitis. These infections are associated with morbidity and mortality rates of up to 28%. Therapy for RSV infections in HCT patients consists primarily of supportive care. Aerosolized ribavirin, or RBV, is FDA-approved for the treatment of RSV but is logistically difficult to administer, as it requires a specialized nebulization device that connects to an aerosol tent surrounding the patient.

Influenza

Influenza infections have been found in up to 46% of allogeneic HCT patients. Approximately 20% of HCT patients with influenza infections progress to develop pneumonia which has been associated with a 30-day mortality rate of 28%. Influenza infections are a major cause of morbidity and mortality in individuals who have weakened immune systems, the elderly and patients with chronic diseases. While there are preventative vaccines for influenza, they are only partially effective in HCT patients. Available antiviral drugs are associated with the development of drug resistance at high rates in HCT patients.

PIV

PIV primarily affects young children and can cause upper respiratory tract infections and lower respiratory tract infections including conditions such as the common cold, croup, bronchitis, bronchiolitis and pneumonia. In immunocompetent individuals the course of these infections is limited due to antiviral responses from both the innate and adaptive immune systems. Up to 18% of immunocompromised HCT patients develop PIV infections, which can lead to decreased lung function, multiorgan failure and graft loss. Mortality rates of HCT patients with PIV infections can be as high as 60%. There are currently no FDA- or EMA-approved vaccines or treatments for PIV infections.

hMPV

Between 5-9% of HCT patients develop hMPV infections. hMPV is a ubiquitous virus to which nearly the entire population globally has been exposed by age five. In the majority of cases, hMPV results in upper respiratory infections with symptoms similar to that of the common cold. In 21-40% of hMPV infections in HCT patients, however, the viral infection progresses from a mild upper respiratory disease to a serious lower respiratory disease that is associated with fatality rates of up to 80%. There are currently no FDA- or EMA-approved therapies or vaccines for hMPV.

Clinical Development Plan

A Phase 1/2 clinical trial of posoleucel in autologous and allogeneic HCT patients with respiratory viral diseases was initiated in 2022. This proof of concept trial was designed as a Phase 1/2, double-blind, placebo-controlled, dose escalation and expansion trial of ALVR106 in addition to standard of care to assess safety and efficacy of ALVR106. Part A of the trial has now completed enrollment, but we have paused development of ALVR106, including discontinuing the trial pending the outcome of our review of strategic alternatives.

Respiratory Virus Infections in High-risk Populations: Elderly, Young, Cancer Patients

In developed countries, there are well-defined high-risk populations in whom RSV infection is more likely to progress into a severe lower respiratory tract infection, including infants less than three months of age or born prematurely, the elderly and immunosuppressed patients. In children, bronchiolitis and pneumonia are the most common clinical manifestations. RSV is responsible for between approximately 66,000 and 199,000 deaths each year. In adults, RSV infections develop annually in 3-7% of elderly individuals and in 4-10% of high-risk adults, where they can cause pneumonia and bronchitis and may lead to death. Importantly, previous infection does not confer immunity. To date, there is no FDA- or EMA-approved vaccine and no clear evidence that treatment with antiviral agents or anti-inflammatory agents reduces the length of infection or the duration of hospital stay in any population. A neutralizing monoclonal antibody, palivizumab, has been developed as immunoprophylaxis to prevent RSV infection; however, its use is limited to high-risk infants because evidence of its effectiveness is limited in broader patient populations.

Influenza

Influenza virus infection causes substantial morbidity and mortality. The World Health Organization, or WHO, estimates that annual epidemics cause 3-5 million cases of severe illness worldwide, and influenza-associated respiratory deaths are estimated to be between approximately 290,000 and 650,000 persons annually. Of these, the highest mortality rates are observed in people aged 75 years and older (51.3 to 99.4 individuals per 100,000). The overall rate of respiratory-associated deaths is also relatively high in patients less than five years of age (2.1 to 23.8 per 100,000). These events occur despite the availability of vaccines and antiviral therapies for influenza. A recent study in the United States demonstrated that vaccination was only 38% effective for influenza A or B viral infections. In the event of infection, patients may be treated with neuraminidase inhibitors, such as oseltamivir and zanamivir. However, not only must these antivirals be administered early in the disease course, they may induce resistance to the influenza virus.

PIV

PIV is among the most common respiratory tract infection worldwide and is associated with both upper and lower respiratory tract infections in both children and adults. Progression from upper to lower respiratory tract infection is most common in children less than five years old and in immunocompromised adults, including the elderly and those with hematologic malignancies. In children, seasonal epidemics account for 40% of hospitalizations for lower respiratory tract illness and 75% of croup cases. Overall, 7% of pediatric hospitalizations for febrile respiratory illness in children less than 5 years old are due to PIV. The estimated annual cost of pediatric hospitalization and emergency room visits due to PIV is greater than $200 million, according to a 2016 study. PIV accounts for 15% of respiratory illness in adults and most commonly manifests as upper respiratory tract infections or pneumonia. Approximately 2.0-11.5% of adult hospitalizations for respiratory illnesses are due to PIV. Currently there are no FDA- or EMA-approved vaccines or antiviral therapies for PIV, and treatment of infection consists of supportive care.

hMPV

Similar to other respiratory pathogens, hMPV causes both upper and lower respiratory tract infections with the most severe disease observed in infants, young children, the elderly, and immunocompromised patients. The most common diagnoses associated with hMPV are bronchiolitis and pneumonia. Studies in children either in the hospital or seen in the outpatient setting show that hMPV is associated with between 6% and 40% of acute respiratory illness. Similar to other respiratory viruses, exposure does not confer immunity, and despite almost all people having been infected with hMPV by age five, re-infection occurs throughout adulthood and is associated with morbidity and mortality in the elderly population. In one study, 46% of hMPV cases were seen in patients greater than 65 years of age and 60% of these patients were hospitalized. In a separate study in an elderly care center, 50% of infected patients developed bronchitis or pneumonia, which led to 50% mortality. Currently there are no FDA- or EMA-approved vaccines or antiviral therapies for hMPV, and treatment of infection consists of supportive care.

Clinical Development Plan

We have paused clinical development of ALVR106, which includes discontinuing the trial pending the outcome of our review of strategic alternatives.

Commercial Opportunity

ALVR106 is an allogeneic, off-the-shelf VST therapy candidate designed to target four common respiratory viruses that represent important causes of morbidity and mortality in HCT and SOT patients, as well as other high-risk patient populations.

ALVR106 for Transplant Patients

In HCT patients, respiratory viral infections occur in both allogeneic HCT and autologous HCT patients. Respiratory viruses infect patients both within the first year post-transplant and beyond. Our target population for ALVR106 includes patients who have undergone allogeneic and autologous HCTs and who have lower respiratory tract infections and upper respiratory tract infections at medium or high risk of progressing to lower respiratory tract infections.

We project the number of allogeneic and autologous HCT procedures to grow 3% annually to approximately 42,000 and 51,000 procedures annually, respectively, by 2025 in our target markets in North America, Europe, Asia Pacific and Latin America. By 2025, we estimate there will be nearly 16,000 HCT patients annually infected with one of the four respiratory viruses targeted by ALVR106. We believe that ALVR106 will be effective for treating infections in HCT patients with one or more of the targeted respiratory viruses.

Respiratory viruses can infect patients of all types of SOTs, although the majority of the literature describes devastating consequences in lung transplant patients. Our initial target population will include lung transplant patients hospitalized for respiratory viruses.

We project the number of new lung transplants to grow 2% annually to approximately 7,000 new lung transplants annually by 2025 in our target markets. We estimate the size of the prevalent lung transplant population to be nearly 56,000 patients in our target markets. By 2025, we estimate that there are annually over 12,000 lung transplant patients that are infected with one of the four respiratory viruses targeted by ALVR106.

ALVR106 for High-risk Populations: Elderly, Young, Cancer Patients

We believe transplant patients represent only a small fraction of the large number of patients suffering from devastating respiratory infections who could potentially benefit from ALVR106. Other individuals with weakened immune systems, including those with primary immunodeficiencies, the elderly and very young and patients who have compromised immune systems due to cancer or the treatment of their cancer are all at high risk of the severe consequences of respiratory infections. Each of these target patient populations represents a large potential market that is currently untapped or underserved by existing therapies.

ALVR107: VST Therapy for the Treatment of Hepatitis B Virus

Hepatitis B Virus

The global prevalence of HBV has been estimated to be between 292 and 360 million people with approximately 260 million people living with chronic HBV infection. HBV is most common in the Western Pacific and African regions, where approximately 6% of the adult population is infected. In contrast, only approximately 1.6% and 0.7% of the European and Americas regions, respectively, are infected. About 30% of patients with chronic HBV develop liver cirrhosis, and nearly 23% of these die within five years of developing cirrhosis.

Current treatment options for chronic HBV consist of life-long antiviral therapy to suppress virus replication. This can slow the progression of liver cirrhosis and reduce the incidence of liver cancer. However, there are no curative therapies available.

Chronic HBV infection is associated not only with significant morbidity and mortality as noted above, but also with weak or absent endogenous HBV-specific T-cell reactivity. In contrast, clinical recovery and effective antiviral therapy are associated with sustained viral control by HBV-specific T cells. Therefore, an off-the-shelf VST therapy that could cure HBV would meet a critical unmet medical need.

POC for the potential of adoptive T cell therapy to achieve functional HBV cure has already been established. A Taiwanese study published in Blood in 2005 demonstrated that 65% of chronic hepatitis B patients who underwent allogeneic HCT transplantation and received cells from a donor with natural HBV immunity, achieved functional HBV cure post-transplant.

ALVR107

ALVR107 is an allogeneic, off-the-shelf VST therapy designed to cure patients with HBV. ALVR107 is comprised of a bank of VSTs manufactured from eligible third-party healthy donors who are pre-screened for infectious agents and disease risk factors. These donors are chosen to reflect and accommodate the HLA diversity of the patient population.

Clinical Development Plan

Preclinical and IND-enabling studies of ALVR107 to treat and cure HBV were completed in 2022 to support advancement into a POC study. Clinical development of ALVR107 is currently paused pending the outcome of our review of strategic alternatives.

Competition

The biopharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. While we believe that our innovative and proprietary technology, the expertise of our executive and scientific team, and our access to cell therapy process development and manufacturing expertise at ElevateBio and BaseCamp provide us with competitive advantages, we face potential competition from many different sources, including pharmaceutical and biotechnology companies, academic institutions and public and private research institutions. VST therapies that we successfully develop and intend to commercialize may compete with existing therapies and new therapies that may become available in the future.

Many of our competitors, either alone or with their collaborators, may have a more established presence in the market and significantly greater financial, technical and human resources than we have. The competitors also compete with us in recruiting and retaining qualified scientific, sales, marketing and management personnel. Smaller or early-stage companies may also prove to be significant competitors through collaborative arrangements with large and established companies.

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, or are less expensive than any products that we may develop. Our competitors

may also obtain FDA or other regulatory approval for their products faster 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.

If approved, our VST therapies would compete with cell therapies and antivirals used to treat and prevent the viral diseases our VST therapies target.

Cell Therapies

There are currently no FDA-approved cell therapies for treating or preventing the viral diseases and infections we are targeting. Atara Biotherapeutics, Inc.'s Ebvallo™ (tabelecleucel), an off-the-shelf, allogeneic T-cell immunotherapy, for HCT and SOT patients with EBV+PTLD (EBV-associated post-transplant lymphoproliferative disease), received European marketing authorization in December 2022.

Antivirals

There are currently no FDA or EMA-approved antiviral therapies for treating most viral diseases and infections in the post-transplant setting, and current antiviral therapies are associated with significant toxicity, including renal insufficiency and bone marrow suppression. Despite the availability of antivirals for some of the viral diseases we are targeting, patients continue to experience high levels of morbidity and mortality. Additionally, the effectiveness of these antivirals is limited due to the emergence of drug resistance. Similarly, there are limitations to prophylactic approaches, such as vaccines, which may not work well in immunosuppressed patients, the elderly, and the very young who are unable to mount an effective immune response. The antiviral therapies currently available for the indications we are targeting with our allogeneic, off-the-shelf VST therapy candidates are listed below. Unless otherwise noted, there are no antiviral therapies approved by the FDA for the treatment or prevention of the viral diseases we are targeting:

Posoleucel: With the exception of valganciclovir, ganciclovir and letermovir for the prevention of CMV disease, and maribavir for the treatment of refractory CMV infection/disease, there are no products FDA-approved for the treatment of AdV, EBV, BKV, HHV-6, or CMV infections or their consequent diseases in allogeneic HCT or SOT patients. Furthermore, there are currently no FDA- or EMA-approved antiviral therapies for the prevention of multiple-viral diseases or infections in transplant patients. Cidofovir is sometimes used off-label for the treatment of BKV-associated HC and AdV infections in HCT patients. Additionally, Vera Therapeutics has completed a Phase 2 clinical trial for MAU868 for the treatment of BKV in KT patients and is exploring the development of MAU868 for the treatment of BKV cystitis in HCT recipients. Memo Therapeutics' AntiBKV, a therapeutic antibody candidate, is in Phase 2 development for the treatment of BKV infection in renal transplant patients. Helocyte, Inc. is conducting Phase 2 clinical trials of its Triplex vaccine to control CMV infections in HCT patients. Rituximab, an approved antiviral treatment for rheumatoid arthritis and B-cell non-Hodgkin's lymphoma, is used off-label for the treatment of EBV infections in HCT and SOT patients. Brincidofovir, a lipid conjugate of cidofovir, is in clinical development by SymBio Pharmaceuticals for the treatment of adenoviral disease after allogeneic HCT. AiCuris has in early development AIC468 to prevent BK viral infection in transplanted kidneys. Finally, intravenous immunoglobulin (IVIG) has been explored for the prevention and treatment of BKV associated nephropathy in renal transplant patients, but not in HCT patients. Even in renal transplant patients, there is limited efficacy data for IVIG to support routine use.

ALVR106: The FDA has approved two vaccines for the prevention of lower respiratory tract disease caused by RSV in individuals 60 and older: Arexvy and Abrysvo. The FDA has approved ribavirin (aerosol) to treat RSV infections in children and pavilizumab to treat RSV infections in children younger than two years old. Ribavirin is also used off-label for the treatment or prevention of RSV infections in HCT and SOT patients and PIV infections and hMPV infections in HCT patients. The FDA has approved the monoclonal antibody Beyfortus (nirsevimab) to treat RSV infections in immunocompromised children. Certain approved antiviral medications, including oseltamivir, zanamivir, baloxavir and peramivir, are used to treat influenza infections in HCT and SOT patients. Ansun BioPharma, or Ansun, is conducting Phase 3 clinical trials of DAS181 to treat influenza infections. Several vaccines are FDA-approved and in clinical development for the prevention of influenza infections. Ansun is also conducting Phase 3 clinical studies of DAS181 to treat PIV infections in immunocompromised patients.

ALVR107: There are numerous antiviral therapies approved by the FDA and in clinical development for the treatment of chronic HBV infections. However, these current treatment options for chronic HBV consist of life-long antiviral therapy to suppress virus replication. This can slow the progression of liver cirrhosis and reduce the incidence of liver cancer, but there are no curative therapies available.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining, maintaining, defending, and enforcing patent protection in the United States and internationally for our proprietary technology, improvements, platforms, product candidates and components thereof, novel biological discoveries, new therapeutic approaches and potential indications, and other inventions that are important to our business. For our product candidates, generally we initially pursue patent protection covering compositions of matter, methods of production, and methods of use. Throughout the development of our product candidates, we will

seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including through additional pharmaceutical formulations, methods of use and production.

As of January 18, 2024, our patent portfolio includes ten patent families exclusively in-licensed from Baylor College of Medicine, or BCM, in our field (one of which is co-owned by AlloVir) and one patent family wholly owned by us. These families include issued and pending patents related generally to allogeneic, off-the-shelf, single and multi-VST cell therapies, and specifically to posoleucel, ALVR106 and ALVR109, various potential preclinical product candidates including ALVR107 and ALVR108, and clinical and backup processes for generating VST-cell products and banks. Specifically, we wholly own two pending PCT applications and exclusively in-license at least five issued U.S. patents, 57 patents issued in foreign jurisdictions, and 87 patent applications pending worldwide. Our issued patents are expected to expire between 2030 and 2036, and any patents that may issue from our pending patent applications are expected to expire between 2030 and 2043, absent any patent term adjustments or extensions. As to the patent term extension to restore patent term lost during product development and the FDA regulatory review process, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval.

Our portfolio related to posoleucel includes two patent families exclusively in-licensed from BCM, directed to multi-VST compositions and methods of making and using such compositions therapeutically. The first family includes two issued U.S. patents with claims directed to our clinical and backup methods of making multi-VST cell lines and related patent applications are pending in the U.S. and Europe. Patents in this family are expected to expire in 2030, absent any patent term adjustments or extensions. The second family includes one issued U.S. patent with claims directed to methods of making posoleucel, one issued European patent with claims directed to methods of making multi-VST compositions including posoleucel and ALVR106, and a second issued European patent with claims directed to compositions of multi-VST compositions including posoleucel and ALVR106, made via such methods. The first European patent is validated in 19 European states, and the second in 21 European States, each including Denmark, France, Germany, Spain and the UK. Related patent applications are pending in the U.S. and in Europe. Patents in this family are expected to expire in 2033, absent any patent term adjustments or extensions as noted above. Our portfolio related to posoleucel also includes one patent family wholly owned by us with two pending PCT applications directed to doses and dosing regimens for treating BK viremia and BK disease in subjects, including solid organ transplant patients using VST compositions such as posoleucel. As part of our alternative strategic direction, we are still assessing whether we will proceed with nationalizing and prosecuting these PCT applications. However, if we do, patents in this family are expected to expire between 2042 and 2043, absent any patent term adjustments or extensions.

Our portfolio related to our ALVR106 product candidate includes the two patent families discussed above with respect to posoleucel as well as a patent family directed to the ALVR106 product and methods of making and using the same therapeutically. This patent family includes one U.S. pending patent application and pending patent applications in Australia, Canada, Europe, and Japan. Any patents that may issue from this patent application are expected to expire in 2040, absent any patent term adjustments or extensions. Additionally, our portfolio related to our ALVR106 product candidate includes a patent family with one allowed U.S. patent application and other applications pending in ex-U.S. jurisdictions with claims directed to VSTs targeting ALVR106 antigens hMPV and PIV. The U.S. patent, once issued, and any patents that may issue from the pending patent applications are expected to expire in 2036, absent any patent term adjustments or extensions.

Our portfolio licensed from BCM also includes a patent family related to our ALVR109 product candidate and methods of treating COVID-19 and other coronavirus infections using the same. This patent family includes one U.S. pending patent application, and 1 pending patent applications in Europe. Any patents that may issue from the patent applications in this family are expected to expire in 2041, absent any patent term adjustments or extensions.

Our portfolio licensed from BCM also includes one patent family related to VST compositions, including our ALVR107 and ALVR108 product candidates, and methods of making and using the same therapeutically. This patent family includes one pending PCT application, and one pending application in Taiwan. Any patents that may issue from the patent applications in this family are expected to expire in 2042, absent any patent term adjustments or extensions.

Our portfolio further includes other patent families related to our VST technologies. For example, our portfolio includes one patent family that includes one pending patent application in each of the U.S. and Europe related to our process of selecting donors for VST generation and our methods of matching patients with suitable VST-cell lines; one patent family that includes one pending patent application in each of the U.S. and Europe related to methods for the prophylactic treatment of viral infections; one patent family with one issued U.S. patent, five issued foreign patents, and pending patent applications in the U.S. and foreign jurisdictions including Australia, Canada, Europe, and Japan, directed to methods of identifying peptides that are likely to be immunogenic or, as is discussed already above, directed to VSTs targeting ALVR106 antigens hMPV and PIV; one patent family including one pending patent application in each of the U.S. and Europe directed to universal antigen-specific T cells compositions and methods of making and using the same; and one patent family including 11 issued patents (including a European patent validated in 7 European states) and 4 pending patent applications with claims directed to methods of rapidly expanding T-cells. Patents in the T-cell expansion family are expected to expire in 2032, and any patents that may issue from the immunogenicity family, the donor selection family, the methods for prophylactic treatment family, or the universal antigen-specific T cell family are expected to expire in 2036, 2040, 2040, and 2041, respectively, absent any patent term adjustments or extensions.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the U.S. Patent and Trademark Office, or the USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as noted, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval.

We also rely on trade secrets relating to product candidates and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. It is our policy to require our employees, consultants, outside scientific partners, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees and consultants also provide that all inventions conceived by the employee or consultant in the course of employment or consulting relationships with us or from the employee's or consultant's use of our confidential information are our exclusive property and require such employees and consultants to assign their title, right and interest in such inventions to us. Although we take steps to protect our proprietary information and trade secrets, including through such contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, including through breaches of such agreements with our employees and consultants. Thus, we may not be able to meaningfully protect our trade secrets.

Sponsored Research, Collaboration, License and Other Agreements

Amended and Restated Exclusive License Agreement with BCM

In June 2017, we signed a License Agreement, or the License Agreement, with BCM, whereby we acquired a royalty-bearing, worldwide, exclusive license to BCM's rights in Subject Technology and related patent rights in the field of viral infection. In May 2020, we entered into an amended and restated exclusive license agreement, or the A&R License Agreement, with BCM, pursuant to which we obtained (a) an exclusive worldwide license, with the right to sublicense, under certain patent rights and other intellectual property rights of BCM, to make, have made, use, market, sell, offer to sell, lease, import and export products in a particular field, except that such license is non-exclusive within a particular subfield, and in addition with respect to certain patent rights such license is limited to two particular subfields, and (b) an exclusive, worldwide sublicense, with the right to further sublicense, under all patent rights and other intellectual property rights that are exclusively licensed to BCM by a certain third party licensor, to make, have made, use, market, sell, offer to sell, lease, import and export products in the same field. Our rights are subject to the rights of the U.S. government and certain rights retained by BCM.

Unless earlier terminated, the A&R License Agreement will expire on a country-by-country basis with respect to a product upon the later of (a) the expiration of the last to expire valid claim of a patent or patent application covering such product in such country or (b) 10 years after the first commercial sale of such product in such country. We may terminate the A&R License Agreement in its entirety at any time for convenience upon a certain number of days' written notice. BCM may terminate the A&R License Agreement in its entirety for our uncured material default.

BCM maintains control of all filing, prosecution and maintenance of its patent rights licensed by us, and we are responsible for all related costs and expenses during the term of the agreement. We also reimbursed BCM for costs and expenses (including reasonable legal fees and expenses) incurred prior to the effective date of the agreement with respect to the filing, prosecution and maintenance of the patent rights licensed by us. If BCM licenses the patent rights licensed by us to third parties for additional fields of use, our responsibility for patent-related costs and expenses will be reduced on a pro-rata basis.

Under the A&R License Agreement, we must use commercially reasonable efforts to develop and commercialize one or more products in certain countries. As partial consideration for the rights conveyed by BCM under the original agreement executed in June 2017, we paid BCM a non-refundable license fee of $250,000. During the term of the A&R License Agreement, we are obligated to pay BCM a non-refundable annual license maintenance fee of $20,000 on the first through fourth anniversaries of the original agreement date and $40,000 beginning on the fifth anniversary of the original agreement date, but beginning with the fifth anniversary of the original agreement date, license maintenance fees are fully creditable against royalty revenue due in the applicable year. We are required to pay certain milestone payments upon the achievement of specified clinical, regulatory, and sales milestones. In the event that we are able to successfully develop, launch and commercialize a product under the A&R License Agreement, total milestone payments could exceed $40.0 million. BCM is also eligible to receive tiered royalties at percentage rates ranging from less than 1% to the low single-digits, on net sales of any products that are commercialized by us or our sublicensees that incorporate, utilize or are made with the use of, the intellectual property licensed by us. To the extent we sublicense our license rights under the A&R License Agreement, BCM would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits.

In November 2020, we entered into the First Amendment, or the License Amendment, to the A&R License Agreement. Under the License Amendment, we assumed responsibility from BCM for the filing, prosecution and maintenance of the patent rights licensed by us from BCM under the A&R License Agreement that are in common with the License Agreement. Further, BCM also transferred to us the right of enforcement against third parties for any suspected infringement of any claims in such patent rights or misuse, misappropriation, theft or breach of confidence of other proprietary rights.

Exclusive License Agreement with BCM

In November 2020, we signed a second License Agreement, or the Second License Agreement, with BCM, whereby we acquired a royalty-bearing, worldwide, exclusive license to BCM's rights in Subject Technology and related patent rights outside the field of viral infection (all fields other than those covered by the License Agreement Amendment noted above).

Unless earlier terminated, the Second License Agreement will expire on a country-by-country basis with respect to a product upon the later of (a) the expiration of the last to expire valid claim of a patent or patent application covering such product in such country or (b) 10 years after the first commercial sale of such product in such country, provided that the Second License Agreement shall not expire later than March 25, 2040. We may terminate the Second License Agreement in its entirety at any time for convenience upon a certain number of days' written notice. BCM may terminate the Second License Agreement in its entirety for our uncured material default.

Under the Second License Agreement, BCM transferred to us control of all filing, prosecution and maintenance of the patent rights licensed by us, and we are responsible for all related costs and expenses during the term of the Second License Agreement. BCM also transferred to us the right of enforcement against third parties for any suspected infringement of any claims in the patent rights or misuse, misappropriation, theft or breach of confidence of other proprietary rights. We also reimbursed BCM for costs and expenses (including reasonable legal fees and expenses) incurred prior to the effective date of the Second License Agreement with respect to the filing, prosecution and maintenance of the patent rights licensed by us, to the extent not already paid by us under the A&R License Agreement.

Under the Second License Agreement, we must use commercially reasonable efforts to develop and commercialize one or more products in certain countries. As partial consideration for the rights conveyed by BCM under the Second License Agreement, we paid BCM a non-refundable license fee of $125,000. During the term of the Second License Agreement, we are obligated to pay BCM a non-refundable annual license maintenance fee of (a) $20,000 for the first through fourth anniversary of the effective date of the Second License Agreement, and (b) $40,000 for the fifth anniversary of the effective date and continuing thereafter, but beginning with the fifth year, license maintenance fees are fully creditable against royalty revenue due in the applicable year. We are required to pay certain milestone payments upon the achievement of specified clinical, regulatory, and sales milestones. In the event that we are able to successfully develop, launch and commercialize multiple products under the Second License Agreement, total milestone payments could exceed $30.0 million. BCM is also eligible to receive tiered royalties at percentage rates ranging from less than 1% to the low single-digits, on net sales of any products that are commercialized by us or our sublicensees that incorporate, utilize or are made with the use of, the intellectual property licensed by us. To the extent we sublicense our license rights under the Second License Agreement, BCM would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits.

Sponsored Research Agreement with BCM

In June 2019, we entered into a sponsored research agreement, or SRA-2, with BCM, under which we agreed to pay BCM for performing certain research activities related to virus specific T-cell manufacturing for a one-year period, renewable for an additional one-year term upon written consent of both parties. SRA-2 requires us to make payments to BCM totaling $1.0 million, payable in four equal installments. SRA-2 was amended in March 2020 to include the discovery and development of allogeneic, off-the-shelf, virus specific T-cell therapies to combat SARS-CoV-2, the virus that causes COVID-19. In June 2020, a second amendment was entered into resulting in a no-cost extension through November 30, 2020, upon which the agreement terminated.

Collaboration Agreement with BCM

In November 2020, we entered into a Research Collaboration Agreement, or the Research Agreement, with BCM, under which we agreed to pay BCM for performing certain research activities under the direction of Dr. Ann Leen commencing on January 1, 2021, and continuing for a three-year period thereafter. The Research Agreement requires us to make payments to BCM totaling approximately $6.0 million over the term of the Research Agreement. In August 2023, the term of the Research Agreement was extended for an additional year, expiring December 31, 2024.

Redeemable Preferred Stock Redemption Agreement

In September 2018, we entered into a redeemable preferred stock redemption agreement, or Redemption Agreement, to redeem shares of our Series A1 convertible preferred stock held by certain investors, including executive officer Ann Leen, director and former executive officer Juan Vera and entities affiliated with director, Malcolm Brenner and former director, John Wilson (or their affiliates).

Pursuant to the Redemption Agreement, for a period of 20 years from the date of the first commercial sale of Viralym-M by us, we are obligated to make earnout payments to such investors on at least an annual basis. The earnout payments will be 10% of our net sales of Viralym-M, which number will be reduced to a high single-digit percentage if certain events occur. Specifically, royalties due to third parties for the sale of Viralym-M are subtracted from the earnout payments due to the investors. Further, if the investors receive at least $50,000,000 in earnout payments from us during the three-year period after the first commercial sale of Viralym-M, the earnout payment percentage will be reduced.

Manufacturing

Our versatile VST manufacturing platform supports the rapid, robust and scalable generation of single- and multi-virus specific cell therapeutic candidates for clinical use. We leverage Cytokin™, our proprietary algorithm to select donors from whom to generate VSTs such that there is broad patient HLA coverage through an efficient set of donors. Virus-specific T-cells from individual healthy seropositive donors are expanded in a fully good manufacturing practices, or cGMP, compliant process, which is scaled to produce hundreds of patient doses from each manufacturing run. Our VST cell therapies are maintained in a cryopreserved state ready for "off-the-shelf" use. Cytomatch™, our proprietary algorithm for HLA matching, identifies the best VST cell line for each patient. In combination, these elements allow us to efficiently build our global supply chain to serve a growing number of patients who could benefit from our highly innovative off-the-shelf VST therapy candidates.

To facilitate investigational product supply for our posoleucel and ALVR106 clinical trials, we manufacture posoleucel and ALVR106 at external cGMP CMOs and leverage a network of cGLP contract testing laboratories. We believe this approach for our clinical product candidates is most cost-effective at our current clinical phase and production scale and has allowed us to rapidly prepare for clinical trials in accordance with our development plans.

Government Regulation

In the United States, biological products, are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the research, development, clinical trial, testing, manufacturing, quality control, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, marketing, promotion, advertising, post-approval monitoring, and post-approval reporting involving biological products. 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, and we may not be able to obtain the required regulatory approvals.

U.S. Biological Products Development Process

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, or GLPs, and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- submission to the FDA of an application for an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- approval of the protocol and related documentation by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each study may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as good clinical practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- preparation of and submission to the FDA of a biologics license application, or BLA, for marketing approval that includes sufficient evidence of establishing the efficacy, safety, purity, and potency of the proposed biological product for its intended indication, including from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current good manufacturing practices, or cGMPs, 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, or CGTPs, for 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;
- review of the product candidate by an FDA advisory committee, where appropriate and if applicable;
- payment of user fees for FDA review of the BLA (unless a fee waiver applies); and
- FDA review and approval of the BLA, resulting in the licensure of the biological product for commercial marketing.

Before testing any biological product candidate, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, may include laboratory evaluations of product biological characteristics, 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, if applicable.

Prior to beginning the first clinical trial with a product candidate in the United States, an IND must be submitted to the FDA and the FDA must allow the IND to proceed. An IND is an exemption from the FD&C Act that allows an unapproved product candidate to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA allowance that such investigational product may be administered to humans in connection with such trial. Such authorization must be secured prior to interstate shipment and administration. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, must be submitted to the FDA as part of an IND. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. Submission of an IND therefore may or may not result in FDA allowance to begin a clinical trial.

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Under the NIH Guidelines, recombinant and synthetic nucleic acids are defined as: (i) molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell (i.e., recombinant nucleic acids); (ii) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids); or (iii) molecules that result from the replication of those described in (i) or (ii). Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

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

An IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the study at least annually. The IRB must review and approve, among other things, the study protocol and informed consent information to be provided to study subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board or committee, or DSMB. This group provides authorization as to whether or not a trial may move forward at designated check points based on data from the ongoing study that are available to the DSMB members.

Certain information about certain clinical trials must also be submitted within specific timeframes to the NIH for public dissemination on its ClinicalTrials.gov website.

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

- *Phase 1*. The investigational 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 investigational 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*. The investigational product is administered to an expanded patient population 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/benefit ratio of the product and provide an adequate basis for approval and product labeling.

In some cases, FDA may require, or firms may voluntarily pursue, post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, 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 subjects, 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, acting on its own or based on a recommendation from the sponsor's data safety monitoring board, may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. 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.

Concurrent with clinical trials, companies may complete additional animal studies and also must 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 and as applicable CGTP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act 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

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA 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 to determine if it is substantially complete before the FDA accepts it for filing. In most cases, the submission of a BLA is subject to a substantial application user fee, although the fee may be waived under certain circumstances. Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA targets ten months from the date FDA files the application (i.e., the filing date) in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application granted priority review by FDA. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification.

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, pure and potent, for its intended use, and whether the product is being manufactured in accordance with cGMP to ensure its continued safety, purity and potency. The FDA may refer applications for novel biological products or biological products that present difficult or novel questions of safety, efficacy, or quality 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, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA typically 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. Where applicable, the FDA also will not approve

the product if the manufacturer is not in compliance with the CGTPs. These are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products, or HCT/Ps, which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human patient. The primary intent of the CGTP 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 appropriate 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 study requirements and GCP requirements. To ensure cGMP, CGTP 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.

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a novel product (e.g., new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological 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. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, including to subpopulations of patients, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings precautions or interactions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase IV post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product 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 a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product 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 for a particular active ingredient 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 or if the 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. Orphan drug exclusivity does not prevent the 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, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or, as noted above, if the second applicant demonstrates that its product is clinically superior to the approved product with orphan exclusivity or the manufacturer of the approved product is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Orphan drug designation may also entitle a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Expedited Development and Review Programs

The FDA has various programs, including Fast Track designation, breakthrough therapy designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of drugs and biologics that are intended for the treatment of serious or life-threatening diseases or conditions. To be eligible for fast track designation, new drugs and biological product candidates must be intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a fast track product at any time during the clinical development of the product. One benefit of fast track designation, for example, is that the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted if certain conditions are satisfied, including an agreement with the 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.

Under the FDA's breakthrough therapy program, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies 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 the 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. The FDA may take other actions appropriate to expedite the development and review of the product candidate, including holding meetings with the sponsor and providing timely advice to, and interactive communication with, the sponsor regarding the development program.

A product candidate is eligible for priority review if it treats a serious or life-threatening disease or condition and, if approved, would provide a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention of a serious disease or condition. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Under priority review, the FDA's goal is to review an application in six months once it is filed, compared to ten months for a standard review. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Additionally, a product candidate may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity, 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 generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials with due diligence and, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, the FDA is now permitted to require, as appropriate, that such trials be underway prior to approval or within a specific time period after the date of approval for a product granted accelerated approval. In addition, for products being considered for accelerated approval, unless otherwise informed by the FDA, the FDA generally requires, that all advertising and promotional materials intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication. Under FDORA, the FDA has increased authority for expedited procedures to withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

RMAT Designation

As part of the 21st Century Cures Act, enacted in December 2016, Congress created the Regenerative Medicine Advanced Therapy, or RMAT, designation to facilitate an efficient development program for, and expedite review of, a product candidate 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. A sponsor may request that the FDA designate a drug as a RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the drug meets the criteria. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review

or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may, as appropriate, fulfill such requirements through the submission of clinical evidence from clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. Like some of FDA's other expedited development programs, RMAT designation does not change the standards for approval but may help expedite the development or approval process.

Post-approval Requirements

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements, as well as requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. We currently rely, and may continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products.

Manufacturers also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions.

Failure to comply with the applicable United States requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, product detentions or refusal to permit the import or export of the product, restrictions on the marketing or manufacturing of the product, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors or other stakeholders, debarment, restitution, disgorgement of profits, or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products, and those supplying products, ingredients, and components of them, are required to register their establishments with the FDA and certain state agencies, and they 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. Manufacturers and other parties involved in the drug supply chain for prescription drug products must also comply with product tracking and tracing requirements and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or products that are otherwise unfit for distribution in the United States. Additionally, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit 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 biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The U.S. PTO, 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 patents, if and as applicable, 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.

The Affordable Care Act, or ACA, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed reference biological product. This amendment to the PHS Act attempts to minimize duplicative testing. Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or trials. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product, and FDA will not approve an application for a biosimilar or interchangeable product based on the reference biological product until twelve years after the date of first licensure of the reference product. "First licensure" typically means the initial date the particular product at issue was licensed in the United States. Date of first licensure does not include the date of licensure of (and a new period of exclusivity is not available for) a biological product if the licensure is for a supplement for the biological product or for a subsequent application by the same sponsor or manufacturer of the biological product (or licensor, predecessor in interest, or other related entity) for a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device or strength, or for a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and impact of the BPCIA is subject to significant uncertainty.

In addition to exclusivity under the BPCIA, a biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods for all formulations, dosage forms, and indications of the active moiety. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study, provided that at the time pediatric exclusivity is granted there is not less than nine months of term remaining.

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.

U.S. Foreign Corrupt Practices Act, U.K. Bribery Act and Other Laws

The U.S. Foreign Corrupt Practices Act of 1977, or FCPA, prohibits United States corporations and individuals from engaging in certain activities to obtain or retain business or secure any improper advantage, or to influence a person working in an official capacity. It is illegal to pay, offer to pay or authorize the payment of anything of value to any employee or official of a foreign government or public international organization, or political party, political party official, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity. The scope of the FCPA also includes employees and officials of state- owned or controlled enterprises, which may include healthcare professionals in many countries. Equivalent laws have been adopted in other foreign countries that impose similar obligations.

Our operations are also subject to non-United States anti-corruption laws such as the U.K. Bribery Act 2010, or the Bribery Act. As with the FCPA, these laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to

obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as trade control laws.

Failure to comply with the Bribery Act, the FCPA and other anti-corruption laws and trade control laws could subject us to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses.

Government Regulation Outside of the United States

In addition to regulations in the United States, we are subject to a variety of regulations in other jurisdictions governing, among other things, research and development, clinical trials, testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products as well as authorization and approval of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

The requirements and processes 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.

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

Clinical Trials Regulation

Whether or not we obtain FDA approval for 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 European Union, for example, a CTA must be submitted for each clinical trial to each country's National Competent Authority, or NCA, and at least one independent Ethics Committee, or EC, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country's requirements, the corresponding clinical trial may proceed. Under the current regime (the EU Clinical Trials Directive 2001/20/EC and corresponding national laws) all suspected unexpected serious adverse reactions to the investigational drug that occur during the clinical trial have to be reported to the NCA and ECs of the European Union Member State where they occurred.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new Clinical Trials Regulation, which will be directly applicable in all Member States (meaning that no national implementing legislation in each European Union Member State is required), aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications. It is expected that the new Clinical Trials Regulation will come into effect following confirmation of full functionality of the Clinical Trials Information System, the centralized European Union portal and database for clinical trials foreseen by the new Clinical Trials regulation, through an independent audit, which is currently expected to occur in January 2023.

Drug Review and Approval

In the European Economic Area (comprised of the European Union Member States plus Norway, Iceland and Liechtenstein), or EEA, medicinal products, including advanced therapy medicinal products, or ATMPs, are subject to extensive pre- and post-market regulation by regulatory authorities at both the EEA and national levels. Under Article 2(1) of Regulation (EC) No 1394/2007, or the ATMP Regulation, ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products. Somatic cell therapy products comprise cells that have undergone substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, where such cells are to be administered to human beings in order to cure, diagnose or prevent disease. We anticipate that our current development products are somatic cell therapy medical products which would be regulated as ATMPs in the EEA.

To obtain regulatory approval of ATMP in the EEA, we must submit a marketing authorization application, or MAA, under the centralized procedure administered by the European Medicines Agency, or EMA. The centralized procedure provides for the grant of a

single marketing authorization by the European Commission that is valid across all of the EEA. As provided for in the ATMP Regulation, the scientific evaluation of MAAs for ATMPs is primarily performed by a specialized scientific committee called the Committee for Advanced Therapies, or CAT. The CAT prepares a draft opinion on the quality, safety and efficacy of the ATMP which is the subject of the MAA, which is sent for final approval to the Committee for Medicinal Products for Human Use, or CHMP. The CHMP recommendation is then sent to the European Commission, which adopts a decision binding in all EEA Member States. The maximum timeframe for the evaluation of an MAA for an ATMP is 210 days from receipt of a valid MAA, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CAT and/or CHMP. Clock stops may extend the timeframe of evaluation of a MAA considerably beyond 210 days. Where the CHMP gives a positive opinion, the EMA provides the opinion together with supporting documentation to the European Commission, who make the final decision to grant a marketing authorization, which is issued within 67 days of receipt of the EMA's recommendation. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts such a request, the timeframe of 210 days for assessment will be reduced to 150 days (excluding clock stops), but it is possible that the CHMP may revert to the standard time limit for the centralized procedure if it determines that the application is no longer appropriate to conduct an accelerated assessment.

The application used to submit the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, certain specific requirements set out in the ATMP Regulation, for example certain particulars to be contained in the summary of product characteristics. A MAA holder for an ATMP in Europe must also put in place a system to ensure that each individual product, and its starting and raw materials, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the relevant healthcare institution.

Now that the UK (which comprises Great Britain and Northern Ireland) has left the European Union, Great Britain will no longer be covered by centralized marketing authorizations (under the Northern Irish Protocol, centralized marketing authorizations will continue to be recognized in Northern Ireland). All medicinal products with a current centralized marketing authorization were automatically converted to Great Britain marketing authorizations on January, 1 2021. For a period of two years from January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or MHRA, the UK medicines regulator, may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a new Great Britain marketing authorization. A separate application will, however, still be required.

Data and Marketing Exclusivity

The EEA also provides opportunities for market exclusivity. Upon receiving a marketing authorization in the EEA, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents generic or biosimilar applicants from referencing the innovator's preclinical or clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization during a period of eight years from the date on which the reference product was first authorized in the EEA. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity period. The overall ten-year period will be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to authorization, is held to bring a significant clinical benefit in comparison with existing therapies. Even if an innovative medicinal product gains the prescribed period of data exclusivity, another company may market another version of the product if such company obtained marketing authorization based on a MAA with a complete independent data package of pharmaceutical tests, preclinical tests and clinical trials.

Orphan Drug Designation and Exclusivity

Products with an orphan designation in the EEA can receive ten years of market exclusivity, during which time "no similar medicinal product" for the same indication may be placed on the market. A "similar medicinal product" is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. An orphan product can also obtain an additional two years of market exclusivity in the European Union where an agreed Pediatric Investigation Plan for pediatric studies has been complied with. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it meets the following criteria: (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either the prevalence of such condition must not be more than five in 10,000 persons in the European Union when the application is made, or without the benefits derived from orphan status, it must be unlikely that the marketing of the medicine would generate sufficient return in the EEA to justify the investment needed for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EEA, or if such a method exists, the product will

be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Otherwise, orphan medicine marketing exclusivity may be revoked only in very select cases, such as if:

- it is established that a similar medicinal product is safer, more effective or otherwise clinically superior;
- the marketing authorization holder consents to a second orphan medicinal product application; or
- the marketing authorization holder cannot supply enough orphan medicinal product.

From January 1, 2021, a separate process for orphan drug designation will apply in Great Britain. There will be no pre-marketing authorization orphan designation (as there is in the EEA) and the application for orphan designation will be reviewed by the MHRA at the time of the marketing authorization application. The criteria are the same as in the EEA, save that they apply to Great Britain only (e.g. there must be no satisfactory method of diagnosis, prevention or treatment of the condition concerned in Great Britain).

Pediatric Development

In the EEA, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA's Pediatric Committee, or PDCO, and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies, (e.g., because the relevant disease or condition occurs only in adults). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization with the results of pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) even where the trial results are negative. In the case of orphan medicinal products, a two year extension of the orphan market exclusivity. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

PRIME Designation

In March 2016, the European Medicines Agency, or EMA, launched an initiative to facilitate development of product candidates in indications, often rare, for which few or no therapies currently exist. The PRIority Medicines, or PRIME, scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation, where the marketing authorization application will be made through the centralized procedure. Eligible products must target conditions for which where is an unmet medical need (there is no satisfactory method of diagnosis, prevention or treatment in the EEA or, if there is, the new medicine will bring a major therapeutic advantage) and they must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Products from small- and medium-sized enterprises may qualify for earlier entry into the PRIME scheme than larger companies. Many benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and accelerated marketing authorization application assessment once a dossier has been submitted. Importantly, a dedicated Agency contact and rapporteur from the Committee for Human Medicinal Products, or CHMP, or Committee for Advanced Therapies are appointed early in PRIME scheme facilitating increased understanding of the product at EMA's Committee level. A kick-off meeting initiates these relationships and includes a team of multidisciplinary experts at the EMA to provide guidance on the overall development and regulatory strategies. Where, during the course of development, a medicine no longer meets the eligibility criteria, support under the PRIME scheme may be withdrawn.

Post-Approval Controls

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include the following:

- The holder of a marketing authorization must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance, who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

- All new MAAs must include a risk management plan, or RMP, describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies. RMPs and PSURs are routinely available to third parties requesting access, subject to limited redactions.
- All advertising and promotional activities for the product must be consistent with the approved SmPC and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the European Union. Although general requirements for advertising and promotion of medicinal products are established under European Union directives, the details are governed by regulations in each European Union Member State and can differ from one country to another.

Brexit and the Regulatory Framework in the United Kingdom

In June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union (commonly referred to as "Brexit"). Thereafter, in March 2017, the country formally notified the European Union of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The United Kingdom formally left the European Union on January 31, 2020. A transition period began on February 1, 2020, during which European Union pharmaceutical law remained applicable to the United Kingdom, and ended on December 31, 2020. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union Directives and Regulations, Brexit could materially impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom, as the United Kingdom legislation now has the potential to diverge from European Union legislation. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the United Kingdom in the long term. The MHRA has recently published detailed guidance for industry and organizations to follow now the transition period is over, which will be updated as the United Kingdom's regulatory position on medicinal products and medical devices evolves over time.

Coverage and Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the U.S., no uniform policy of coverage and reimbursement for drug or biological products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. 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 or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. The coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

In the United States and in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. The availability of coverage and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford treatments such as cell or gene therapy products. Sales of these or other product candidates that we may identify will depend substantially, both domestically and abroad, on the extent to which the costs of our product candidates will be paid by health maintenance, managed care, and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third-party payors. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory

authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. Factors a payor considers in determining reimbursement are based on whether the 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.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement.

In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs.

Many third-party payors are increasingly limiting both coverage and the level of reimbursement of new drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average sales price, or ASP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. 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. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, products launched in the European Union do not follow price structures of the U.S. and generally prices tend to be significantly lower.

Other Healthcare Laws and Compliance Requirements

In the United States, our current and future operations are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, CMS, other divisions of the United States Department of Health and Human Service, or HHS, (such as the Office of Inspector General, Office for Civil Rights and the Health Resources and Service Administration), the U.S. Department of Justice, or DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. Our clinical research, sales, marketing and scientific/educational grant programs may be subject to the following laws, each as amended, as applicable:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. 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 federal False Claims Act or federal civil money penalties statute;
- the federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional 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, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. 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 of 2009, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, 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. HITECH also created 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, there may be additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;
- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which require applicable manufacturers of drugs, devices, biologics 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 CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed

healthcare practitioners and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members;

- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require pharmaceutical companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of pharmaceutical sales representatives; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; and state and foreign laws that govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Government enforcement agencies have shown increased interest in pharmaceutical companies' product and patient assistance programs, including reimbursement support services, and a number of investigations into these programs have resulted in significant civil and criminal settlements. In addition, at least one insurer has directed its network pharmacies to no longer accept co-pay coupons for certain specialty drugs the insurer identified. In addition, in November 2013, the CMS issued guidance to the issuers of qualified health plans sold through the ACA's marketplaces encouraging such plans to reject patient cost-sharing support from third parties and indicating that the CMS intends to monitor the provision of such support and may take regulatory action to limit it in the future. The CMS subsequently issued a rule requiring individual market qualified health plans to accept third-party premium and cost-sharing payments from certain government-related entities. In September 2014, the OIG of the HHS issued a Special Advisory Bulletin warning manufacturers that they may be subject to sanctions under the federal Anti-Kickback Statute and/or civil monetary penalty laws if they do not take appropriate steps to exclude Part D beneficiaries from using co-pay coupons. Accordingly, companies exclude these Part D beneficiaries from using co-pay coupons. It is possible that changes in insurer policies regarding co-pay coupons and/or the introduction and enactment of new legislation or regulatory action could restrict or otherwise negatively affect these patient support programs, which could result in fewer patients using affected products, and therefore could have a material adverse effect on our sales, business, and financial condition.

Third party patient assistance programs that receive financial support from companies have become the subject of enhanced government and regulatory scrutiny. The OIG has established guidelines that suggest that it is lawful for pharmaceutical manufacturers to make donations to charitable organizations who provide co-pay assistance to Medicare patients, provided that such organizations, among other things, are bona fide charities, are entirely independent of and not controlled by the manufacturer, provide aid to applicants on a first-come basis according to consistent financial criteria and do not link aid to use of a donor's product. However, donations to patient assistance programs have received some negative publicity and have been the subject of multiple government enforcement actions, related to allegations regarding their use to promote branded pharmaceutical products over other less costly alternatives. Specifically, in recent years, there have been multiple settlements resulting out of government claims challenging the legality of their patient assistance programs under a variety of federal and state laws. It is possible that we may make grants to independent charitable foundations that help financially needy patients with their premium, co-pay, and co-insurance obligations. If we choose to do so, and if we or our vendors or donation recipients are deemed to fail to comply with relevant laws, regulations or evolving government guidance in the operation of these programs, we could be subject to damages, fines, penalties, or other criminal, civil, or administrative sanctions or enforcement actions. We cannot ensure that our compliance controls, policies, and procedures will be sufficient to protect against acts of our employees, business partners, or vendors that may violate the laws or regulations of the jurisdictions in which we operate. Regardless of whether we have complied with the law, a government investigation could impact our business practices, harm our reputation, divert the attention of management, increase our expenses, and reduce the availability of foundation support for our patients who need assistance.

On December 2, 2020, the United States Department of Health and Human Service, or HHS, published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers (PBMs), unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between PBMs and manufacturers. Implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and PBM service fees are currently under review by the current U.S. presidential administration and may be amended or repealed. Although

a number of these and other proposed measures may require authorization through additional legislation to become effective, and the current U.S. presidential administration may reverse or otherwise change these measures, both the current U.S. presidential administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Efforts to ensure that our current and future business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. If our operations, including our arrangements with physicians and other healthcare providers, are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, criminal and/or civil penalties, damages, fines, disgorgement, reputational harm, imprisonment, the exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the United States government, and/or the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to similar penalties.

The risk of our being found in violation of these laws is increased by the fact that many of these laws have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain a robust system to comply with multiple jurisdictions with different compliance and reporting requirements increases the possibility that a healthcare company may violate one or more of the requirements. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial cost.

Data Privacy and Security Laws

We may also be subject to data privacy and security laws in the United States and various jurisdictions around the world in which we operate or from which we collect or otherwise process personally identifiable information ("personal information"). In the United States, HIPAA, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA mandates the reporting of certain breaches of personal information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information, a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards.

In addition, certain states govern the privacy and security of health information and/or other personally identifiable information, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted the California Consumer Privacy Act, or CCPA, which created comprehensive individual privacy rights for California consumers (as defined in the law) and placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA required covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020, and the California Attorney General began commencing enforcement actions against violators on July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and/or that is collected, used, or disclosed in clinical trial research, as currently written, the CCPA may still impact our business activities. The uncertainty and enforcement surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. The CCPA may increase our compliance costs and potential liability. The CCPA marks the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

Additionally, a California ballot initiative, the California Privacy Rights Act, or CPRA, was passed in November 2020 and as of January 1, 2023 has imposed additional obligations on companies covered by the legislation. The CPRA significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a new

state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The effects of the CCPA, as modified by the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

Similar laws have been passed in numerous other states and other states have proposed similar new privacy laws. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating health information. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted.

The collection, use, storage, disclosure, transfer, or other processing of personal information regarding individuals in the European Economic Area, or EEA, including personal health data, is subject to the EU GDPR, which became effective on May 25, 2018. Following the United Kingdom's ("UK") withdrawal from the EU ("Brexit"), the EU GDPR has been incorporated into UK laws ("UK GDPR" and together with the EU GDPR, "GDPR"). The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union and the UK, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million (£17.5 million) or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Despite Brexit, the EU and UK GDPR remain largely aligned.Currently, the most impactful point of divergence relates to transfer mechanisms (i.e., the ability for EU/UK companies to transfer personal information to third countries, including the United States), because it requires us to implement a variety of different contractual clauses approved by EU or UK regulators. This complexity and the additional contractual burden increases our overall risk exposure. There may be further divergence in the future, including with regard to administrative burdens. The UK has announced plans to reform the country’s data protection legal framework in its Data Reform Bill, which will introduce significant divergence from the EU GDPR. Compliance with the EU GDPR and UK GDPR is a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European or UK activities.

Additionally, we do business around the world and many other foreign jurisdictions have passed data privacy legislation and others are considering various proposals for new and/or amended privacy and data protection laws. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines and penalties if we are unable to comply. The regulatory framework governing the collection, processing, storage, use and sharing of certain information is rapidly evolving and is likely to continue to be subject to uncertainty and varying interpretations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our existing data management practices or the features of our services and platform capabilities. Any failure or perceived failure by us, or any third parties with which we do business, to comply with our posted privacy policies, evolving laws, rules and regulations, industry standards, or contractual obligations to which we or such third parties are or may become subject, may result in actions or other claims against us by governmental entities or private actors, the expenditure of substantial costs, time and other resources or the incurrence of significant fines, penalties or other liabilities. In addition, any such action, particularly to the extent we were found to be guilty of violations or otherwise liable for damages, would damage our reputation and adversely affect our business, financial condition and results of operations.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in 2010, the ACA, was enacted

which includes changes to the coverage and payment for products under government health care programs. Among other things, the ACA:

- increases the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program;
- extends the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans;
- establishes annual fees and taxes on manufacturers of certain branded prescription drugs;
- creates a new Medicare Part D coverage gap discount program, in which manufacturers must 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 manufacturer's outpatient drugs to be covered under Medicare Part D.; and
- expands the entities eligible for discounts under the PHS Act's pharmaceutical pricing program, also known as the 340B Drug Pricing Program.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. The Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013, and, due to legislation amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will stay in effect through 2031, unless additional Congressional action is taken. On January 2, 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. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. In addition, CMS published a final rule that would give states greater flexibility, as of 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

On March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Due to the Statutory Pay-As-You-Go Act of 2010, estimated budget deficit increases resulting from the American Rescue Plan Act of 2021, and subsequent legislation, Medicare payments to providers will be further reduced starting in 2025 absent further legislation. These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

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 proposed and enacted federal and state legislation 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of these changes on the regulatory approvals of our product candidates, if any, may be. In the U.S., the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices for certain products in certain markets. For example, in the U.S., there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At a federal level, President Biden has issued multiple executive orders that have sought to reduce prescription drug costs. In February 2023, HHS also issued a proposal in response to an October 2022 executive order from President Biden that includes a proposed prescription drug pricing model that will test whether targeted Medicare payment adjustments will sufficiently incentivize manufacturers to complete confirmatory trials for drugs approved through FDA's accelerated approval pathway. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or

otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek new legislative measures to control drug costs.

In August 2022, the IRA was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a $2,000 out-of-pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D pricing for certain high-cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. Further, under the IRA, orphan drugs are exempted from the Medicare drug price negotiation program, but only if they have one orphan designation and for which the only approved indication is for that disease or condition. If a product receives multiple orphan designations or has multiple approved indications, it may not qualify for the orphan drug exemption. The implementation of the IRA is currently subject to ongoing litigation challenging the constitutionality of the IRA's Medicare drug price negotiation program. The effect of IRA on our business and the healthcare industry in general is not yet known. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. Federal Government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Human Capital

As of December 31, 2023, we had 112 full-time employees, including 16 with Ph.D. or M.D. degrees, and 83 who are engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of equity-based compensation awards in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Available Information

Our Internet address is www. allovir.com. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, including exhibits, proxy and information statements and amendments to those reports filed or furnished pursuant to Sections 13(a), 14, and 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, are available through the "Investors" portion of our website free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Information on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, our filings with the SEC may be accessed through the SEC's Interactive Data Electronic Applications system at *http://www.sec.gov*. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should consider carefully the risks and uncertainties described below, in addition to other information contained in this Annual Report on Form 10-K, as well as our other public filings with the Securities and Exchange Commission, or the SEC. Any of the following risks could have a material adverse effect on our business, financial condition, results of operations and growth prospects and could cause the trading price of our common stock to decline.

Risks Related to our Strategic Review Process

We may not be successful in identifying and implementing any strategic transaction and any strategic transactions that we may consummate in the future could have negative consequences.

In December 2023, we announced that we are undertaking a comprehensive review of strategic alternatives focused on maximizing shareholder value, including, but not limited to, a merger, sale, divestiture of assets, in-licensing, options for potential recommencement of our product candidates, or other strategic transaction. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value or that we will make any additional cash distributions to our stockholders.

The process of continuing to evaluate these strategic options may be very costly, time-consuming and complex and we have incurred, and may in the future incur, significant costs related to this continued evaluation, such as legal and accounting fees and expenses and other related charges. We may also incur additional unanticipated expenses in connection with this process. A considerable portion of these costs will be incurred regardless of whether any such course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business.

In addition, potential counterparties in a strategic transaction involving our company may place minimal or no value on our assets and our public listing. Further, should we resume the development of our product candidates, the development and any potential commercialization of our product candidates will require substantial additional cash to fund the costs associated with conducting the necessary preclinical and clinical testing and obtaining regulatory approval. Consequently, any potential counterparty in a strategic transaction involving our company may choose not to spend additional resources and continue development of our product candidates and may attribute little or no value, in such a transaction, to those product candidates.

In addition, any strategic business combination or other transactions that we may consummate in the future could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. Any potential transaction would be dependent on a number of factors that may be beyond our control, including, among other things, market conditions, industry trends, the interest of third parties in a potential transaction with us, obtaining stockholder approval and the availability of financing to third parties in a potential transaction with us on reasonable terms. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

If we are not successful in setting forth a new strategic path for the Company, or if our plans are not executed in a timely fashion, this may cause reputational harm with our stockholders and the value of our securities may be adversely impacted. In addition, speculation regarding any developments related to the review of strategic alternatives and perceived uncertainties related to the future of the Company could cause our stock price to fluctuate significantly.

Even if we successfully consummate any transaction from our strategic assessment, including, but not limited to, a merger, a sale, divestiture of assets and/or licensing, we may fail to realize all of the anticipated benefits of the transaction, those benefits may take longer to realize than expected, or we may encounter integration difficulties.

Our ability to realize the anticipated benefits of any potential business combination or any other result from our strategic assessment, are highly uncertain. Any anticipated benefits will depend on a number of factors, including our ability to integrate with any future business partner and our ability to generate future shareholder value in the platform we may elect to pursue. The process may be disruptive to our business and the expected benefits may not be achieved within the anticipated time frame, or at all. The failure to meet the challenges involved and to realize the anticipated benefits of any potential transaction could adversely affect our business and financial condition.

If we are successful in completing a strategic transaction, we may be exposed to other operational and financial risks.

Although there can be no assurance that a strategic transaction will result from the process we have undertaken to identify and evaluate strategic alternatives, the negotiation and consummation of any such transaction will require significant time on the part of our management, and the diversion of management's attention may disrupt our business.

The negotiation and consummation of any such transaction may also require more time or greater cash resources than we anticipate and expose us to other operational and financial risks, including:

- increased near-term and long-term expenditures;
- exposure to unknown liabilities;
- higher than expected acquisition or integration costs;
- incurrence of substantial debt or dilutive issuances of equity securities to fund future operations;
- write-downs of assets or goodwill or incurrence of non-recurring, impairment or other charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired business with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired business due to changes in management and ownership;
- inability to retain key employees of our company or any acquired business; and
- possibility of future litigation.

Any of the foregoing risks could have a material adverse effect on our business, financial condition and prospects.

If a strategic transaction is not consummated, our board of directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities.

There can be no assurance that a strategic transaction will be completed. If a strategic transaction is not completed, our Board of Directors may decide to pursue a dissolution and liquidation. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such decision and, with the passage of time the amount of cash available for distribution will be reduced as we continue to fund our operations. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation, we would be required under Delaware corporate law to pay our outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to our stockholders. As a result of this requirement, a portion of our assets may need to be reserved pending the resolution of such obligations and the timing of any such resolution is uncertain. In addition, we may be subject to litigation or other claims related to a dissolution and liquidation. If a dissolution and liquidation were pursued, our board of directors, in consultation with our advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of a liquidation, dissolution or winding up.

Our ability to consummate a strategic transaction depends on our ability to retain our employees required to consummate such transaction.

Our ability to consummate a strategic transaction depends upon our ability to retain our employees required to consummate such a transaction, the loss of whose services may adversely impact the ability to consummate such transaction. In connection with the evaluation of strategic alternatives and in order to extend our resources, we implemented a reduction in our workforce by approximately 95%, expected to be completed by April 15, 2024. The strategic review process is supported by our deep and broad experience at the board, executive management, and supporting staff levels. Our cash conservation activities may yield unintended consequences, such as attrition beyond our reduction in workforce and reduced employee morale, which may cause remaining employees to seek alternative employment. Our ability to successfully complete a strategic transaction depends in large part on our ability to retain certain of our remaining personnel. If we are unable to successfully retain our remaining personnel, we are at risk of a disruption to our exploration and consummation of a strategic alternative as well as business operations.

Our corporate restructuring and the associated headcount reduction may not result in anticipated savings, could result in total costs and expenses that are greater than expected and could disrupt our business.

In December 2023, in order to extend its resources, we announced a comprehensive review of strategic alternatives and in connection therewith, we announced a discontinuation of the our three Phase 3 registrational trials of posoleucel, two multicenter, randomized, double-blind, placebo-controlled Phase 3 trials of posoleucel and other clinical development programs and further prioritization of our resources as it assesses strategic alternatives. In January 2024, our Board of Directors approved a reduction its workforce by

approximately 95% in order to reduce costs and preserve capital in light of our announcement in December 2023 that we were discontinuing its three global Phase 3 posoleucel studies. We estimate that we will incur personnel-related restructuring charges of approximately $13 million in connection with one-time employee termination cash expenditures, including severance and other benefits, which are expected to be substantially incurred in the first quarter of 2024. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our cost structure from our restructuring efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the restructuring, our operating results and financial condition would be adversely affected. Furthermore, our restructuring plan may be disruptive to our operations. For example, our headcount reductions could yield unanticipated consequences, such as increased difficulties in implementing our business strategy, including retention of our remaining employees.

Any future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain and integrate additional employees. Due to our limited resources, we may not be able to effectively manage our operations or recruit and retain qualified personnel, which may result in weaknesses in our infrastructure and operations, risks that we may not be able to comply with legal and regulatory requirements, and loss of employees and reduced productivity among remaining employees. For example, the workforce reduction may negatively impact our clinical, regulatory, technical operations, our cybersecurity program, and commercial functions, should we choose to continue to pursue them, which would have a negative impact on our ability to successfully develop, and ultimately, commercialize our product candidates. Our future financial performance and, should we resume development, our ability to develop our product candidates or additional assets will depend, in part, on our ability to effectively manage any future growth or restructuring, as the case may be.

We may become involved in litigation, including securities class action litigation, that could divert management's attention and harm the company's business, and insurance coverage may not be sufficient to cover all costs and damages.

In the past, litigation, including securities class action litigation, has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, or the announcement of negative events, such as negative results from clinical trials. These events may also result in investigations by the SEC. We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Risks Related to the Clinical Development, Regulatory Review and Approval of Our Product Candidates

Risks Related to Clinical Development

We are early in our development efforts and have only a small number of product candidates in clinical development. All of our other product candidates are still in preclinical development. If we or our collaborators are unable to successfully develop and commercialize product candidates or experience significant delays in doing so, our business may be materially harmed.

We are early in our development efforts, and only a small number of our product candidates are in or are entering into clinical development. The majority of our product candidates are currently in preclinical development. We have invested substantial resources in identifying and developing potential product candidates, conducting preclinical studies and clinical trials and developing an efficient and scalable manufacturing process for our product candidates. Our ability to generate revenues, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of our product candidates. Should we resume development of our product candidates, the success of our product candidates and our ability to generate revenues and achieve profitability will depend on many factors, including the following:

- completion of preclinical studies and clinical trials with positive results;
- receipt of regulatory approvals from applicable authorities and successful completion of any post-marketing requirements or commitments;
- protecting our rights in our intellectual property portfolio, including by obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- establishing and maintaining adequate supply of our product candidates, including third-party donor starting material for global clinical trials, raw materials used in the manufacturing process, manufacturing capacity and release testing capacity;
- establishing and qualifying redundant supplies for critical starting materials including third-party donor material, cell culture media, peptides, cytokines, human AB serum and drug product final formulation buffer;
- establishing or making arrangements with third-party manufacturers or completing our own manufacturing facility for clinical and commercial manufacturing purposes;
- developing manufacturing and distribution processes for our multi-VST cell therapy product candidates;

- manufacturing our product candidates at an acceptable cost;
- attracting, hiring and retaining qualified personnel;
- launching commercial sales of our products, if approved by applicable regulatory authorities, whether alone or in collaboration with others;
- acceptance of our products, if approved by applicable regulatory authorities, by patients and the medical community;
- obtaining and maintaining coverage and adequate reimbursement by third-party payors, including government payors, for our products, if approved by applicable regulatory authorities;
- effectively competing with other therapies;
- maintaining a continued acceptable benefit/risk profile of the products following approval; and
- maintaining and growing an organization of scientists and functional experts who can develop and commercialize our products and technology.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully develop and commercialize our product candidates, which could materially harm our business. Our revenues for any of our product candidates for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain reimbursement at any price, and whether we own the commercial rights for such territory. If the addressable patient population in such territory is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenues from sales of our products, even if approved. In addition, we anticipate incurring significant costs associated with commercializing any approved product candidate. As a result, even if we generate revenues, we may not become profitable and may need to obtain additional funding to continue operations. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations as planned and may be forced to reduce or discontinue our operations. In addition, regulators may determine that our financial relationships with our principal investigators, some of whom receive compensation as consultants, in a perceived or actual conflict of interest, may have affected the interpretation of a study, the integrity of the data generated at the applicable clinical trial site or the utility of the clinical trial.

Our future success is dependent on the regulatory approval of our product candidates. The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We have not obtained regulatory approval for any of our product candidates, including our clinical-stage product candidates posoleucel and ALVR106. Should we resume development of our product candidates, our business is substantially dependent on our ability to obtain regulatory approval for, and, if approved, to successfully commercialize our product candidates in a timely manner.

We cannot commercialize product candidates in the United States without first obtaining regulatory approval from the FDA; similarly, we cannot commercialize product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and clinical trials, that the product candidate is safe and effective for use for that target indication and that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure safety, purity and potency.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon numerous factors, including the study designs and substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any product candidate and it is possible that none of our existing product candidates or any future product candidates will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with the design or conduct of our clinical trials;
- failure to demonstrate to the satisfaction of regulatory agencies that our product candidates are safe and effective, or have a positive benefit/risk profile for its proposed indication;
- failure of clinical trials to meet the level of statistical significance required for approval;

- disagreement with our interpretation of data from preclinical studies or clinical trials;
- the insufficiency of data collected from clinical trials of our product candidates to support the submission and filing of a Biologics License Application, or BLA, or other submission or to obtain regulatory approval;
- failure to obtain approval of our manufacturing processes or facilities of third-party manufacturers with whom we contract for clinical and commercial supplies or our own manufacturing facility;
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval; or
- our failure to obtain and retain accurate data in our clinical trials.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or we may decide to abandon the development program. If we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may grant approval contingent on the performance of costly post-marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate.

In addition, the clinical trial requirements of the FDA, the European Medicines Agency, or the 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 our novel multi-VST-cell therapy, can be more complex and consequently more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. There are currently no FDA approved cell-based therapies for the treatment of viral diseases, including those that our product candidates are designed to target. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events.

Risks Related to the Industry

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, 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, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. 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 biological products, or biologics, or modifications to approved biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. 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. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

The regulatory landscape that applies to gene and cell therapy product candidates is rigorous, complex, uncertain and subject to change. Our single- and multi-VST cell therapy product candidates represent new therapeutic approaches that could result in heightened regulatory scrutiny, delays in clinical development or delays in or our ability to achieve regulatory approval, if at all, and commercialization or payor coverage and reimbursement of our product candidates, if approved.

Our future success is dependent on our single- and multi-VST cell therapy approach. Because these programs, particularly our pipeline of allogeneic T cell product candidates that are bioengineered from donors, represent a unique approach to immunotherapy for the treatment of virus-infected cells in order to restore T cell immunity, developing and commercializing our product candidates subjects us to a number of challenges, including:

- obtaining regulatory approval from the FDA and other regulatory authorities, which have limited experience with regulating the development and commercialization of T cell immunotherapies;

- developing and deploying consistent and reliable processes for procuring blood from consenting third-party donors, isolating T cells from the blood of such donors, activating the isolated T cells against specific antigens, characterizing and storing the resulting activated T cells for future therapeutic use, selecting and delivering a sufficient supply and breadth of appropriate partially HLA-matched cell line from among the available T cell lines, and finally infusing these activated T cells into patients to enable the VSTs to recognize and eliminate virus-infected cells in the patient and induce antiviral benefit;
- relying on healthcare provider site availability and accessibility to patients for receipt of T cell infusions;
- utilizing these product candidates in combination with other therapies, including immunomodulatory therapies currently used to treat patients in our target population, which may increase the risk of adverse side effects;
- educating medical personnel regarding the potential side effect profile of each of our product candidates, particularly those that may be unique to our multi-VST cell therapy product candidates;
- understanding and addressing variability in the quality of a VST donor's T cells, which could ultimately affect our ability to manufacture product in a reliable and consistent manner;
- developing processes for the safe administration of these products, including long-term follow-up and registries, for all patients who receive these product candidates;
- manufacturing our product candidates to our specifications and in a timely manner to support our clinical trials and, if approved, commercialization;
- sourcing clinical and, if approved by applicable regulatory authorities, commercial supplies for the materials used to manufacture and process these product candidates that are free from viruses and other pathogens that may increase the risk of adverse side effects;
- developing a manufacturing process and distribution network that can provide a stable supply with a cost of goods that allows for an attractive return on investment;
- establishing sales and marketing capabilities ahead of and after obtaining any regulatory approval to gain market acceptance, and obtaining adequate coverage, reimbursement and pricing by third-party payors and government authorities; and
- developing therapies for types of diseases beyond those initially addressed by our current product candidates.

Regulatory requirements governing the development of gene therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Therapeutic Products, or OTP, within the CBER, to consolidate the review of gene therapy and related products, and to advise the CBER on its review. In addition, under guidelines issued by the National Institutes of Health, or NIH, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, that institution's institutional review board, or IRB, and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Moreover, serious adverse events or developments in clinical trials of gene therapy product candidates conducted by others may cause the FDA or other regulatory bodies to initiate a clinical hold on our clinical trials or otherwise change the requirements for approval of any of our product candidates. Although the FDA decides whether individual cell and gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

Adverse developments in preclinical studies or clinical trials conducted by others in the field of gene therapy and gene regulation products may cause the FDA, the EMA, and other regulatory bodies to amend the requirements for approval of any product candidates we may develop or limit the use of products utilizing gene regulation technologies, either of which could harm our business. In addition, the clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Further, as we are developing novel potential treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the EMA or other regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. The prospectively designed natural history studies with the same endpoints as our corresponding clinical trials may not be accepted by the FDA, EMA or other regulatory authorities. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing gene regulation technology in a timely manner or under technically or commercially feasible conditions. In addition, regulatory action or private litigation could result in expenses, delays, or other impediments to our research programs or the commercialization of resulting products.

We cannot be sure that the manufacturing processes used in connection with our T cell immunotherapy product candidates will yield a sufficient supply of satisfactory products that are safe, pure and potent, comparable to those T cells produced by our partners historically, scalable or profitable.

Moreover, actual or perceived safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved by applicable regulatory authorities, of physicians to subscribe to the novel treatment mechanics. The FDA or other applicable regulatory authorities may ask for specific post-market requirements, such as establishment of a Risk Evaluation and Mitigation Strategy, or REMS, and additional information informing benefits or risks of our products may emerge at any time prior to or after regulatory approval.

Physicians, hospitals and third-party payors are often slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and the inability to successfully and timely conduct clinical trials and obtain regulatory approval for our product candidates would substantially harm our business.

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. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and clinical trials.

We may experience delays in our ongoing or future clinical trials and we do not know whether clinical trials will begin or enroll subjects on time, will need to be redesigned or will be completed on schedule, if at all. Any inability to commence or complete our planned clinical trials of our product candidates as a result of a clinical hold or otherwise, will delay or terminate our clinical development plans for our product candidates, may require us to incur additional clinical development costs and could impair our ability to ultimately obtain FDA approval for our product candidates. Clinical trials may be delayed, suspended or prematurely terminated for a variety of other reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on the design and implementation of clinical trials;
- delay or failure in obtaining authorization to commence a trial, including the delay or ability to generate sufficient preclinical data to support initiation of clinical trials, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a trial;
- delay or failure in 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;
- the inability of CROs to perform under these agreements;
- delay or failure in obtaining IRB approval or the approval of other reviewing entities, including comparable foreign regulatory authorities, to conduct a clinical trial at each site;
- withdrawal of clinical trial sites from our clinical trials or the ineligibility of a site to participate in our clinical trials;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in subjects completing a study or returning for post-treatment follow-up;
- clinical sites and investigators deviating from study protocol, failing to conduct the study in accordance with regulatory requirements, or dropping out of a study;
- inability to identify and maintain a sufficient number of trial sites, including because potential trial sites may already be engaged in competing clinical trial programs for the same indication that we are treating;
- failure of our third-party clinical trial managers to satisfy their contractual duties, meet expected deadlines or return trustworthy data;
- delay or failure in adding new trial sites, including due to changes in policies of the clinical research sites or local IRBs;
- interim results or data that are ambiguous or negative or are inconsistent with earlier results or data;
- feedback from the FDA, the IRB, data safety monitoring boards or comparable foreign authorities, or results from earlier stage or concurrent preclinical studies and clinical trials, that might require modification to the protocol for a study;

- a decision by the FDA, the IRB, comparable foreign authorities, or us, or a recommendation by a data safety monitoring board or comparable foreign authority, to suspend or terminate clinical trials at any time for safety issues or for any other reason;
- unacceptable benefit/risk profile, unforeseen safety issues or adverse side effects;
- failure to demonstrate a benefit from using a product candidate;
- difficulties in finding subjects from whom to obtain cell lines;
- difficulties in locating cell lines for which it is difficult to find a match;
- difficulties in manufacturing or obtaining from third parties sufficient quantities and breadth of appropriate partially HLA matched cell lines from among the available T cell lines to start or to use in clinical trials;
- lack of adequate funding to continue a study, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional studies or increased expenses associated with the services of our CROs and other third parties; or
- changes in governmental regulations or administrative actions, failure by us or third parties to comply with regulatory requirements, or lack of adequate funding to continue a clinical trial.
- Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including:
- the size and nature of the patient population;
- the possibility that the viral diseases that many of our product candidates address are under-diagnosed;
- changing medical practice patterns or guidelines related to the indications we are investigating;
- the severity of the disease under investigation, our ability to open clinical trial sites;
- the proximity of subjects to clinical sites;
- delays in or temporary suspension of the enrollment of patients in our ongoing and planned clinical trials due to pandemics such as COVID-19;
- the patient referral practices of physicians;
- the design and eligibility criteria of the clinical trial;
- ability to obtain and maintain patient consents;
- risk that enrolled subjects will drop out or die before completion;
- competition for patients from other clinical trials;
- our ability to manufacture the requisite materials for a trial;
- risk that we do not have appropriately matched HLA cell lines; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new product candidates that may be approved for the indications we are investigating.

In addition, we could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination 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 comparable foreign 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 drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

We currently rely on CROs, other vendors and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance.

Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Additionally, we or our collaborators may experience unforeseen events during or resulting from clinical trials that could delay or prevent receipt of marketing approval for or commercialization of product candidates. If we or our collaborators are required to conduct additional clinical trials or other testing of product candidates beyond those that we or our collaborators currently contemplate, if we or our collaborators are unable to successfully complete clinical trials or other testing of such product candidates, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining or fail to obtain marketing approval for product candidates;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered;
- have regulatory authorities withdraw or suspend their approval of the product or impose restrictions on its distribution;
- be sued; or
- experience damage to our reputation.

If we experience delays or quality issues in the conduct, completion or termination of any clinical trial of our product candidates, the approval and commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any delays in completing our clinical trials for our product candidates may also decrease the period of commercial exclusivity. In addition, many of the factors that could cause a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

The results of preclinical studies or earlier clinical trials are not necessarily predictive of future results. Should we resume development of our product candidates, our existing product candidates in clinical trials, and any other product candidate we advance into clinical trials, may not have favorable results in later clinical trials or receive regulatory approval.

Success in preclinical studies and early clinical trials does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of any of our product candidates. For example, in December 2023, we announced the discontinuation of three Phase 3 registrational trials of posoleucel following separate, pre-planned DSMB futility analyses concluded the studies were unlikely to meet their primary endpoints. Specifically, we discontinued a multicenter, randomized, double-blind, placebo-controlled Phase 3 trial comparing posoleucel to placebo for the prevention of infection or disease due to AdV, BKV, CMV, EBV, HHV-6, or JCV in high-risk adult and pediatric patients after undergoing an allogeneic hematopoietic stem cell transplant. We also discontinued two multicenter, randomized, double-blind, placebo-controlled Phase 3 trials of posoleucel – one for the treatment of virus-associated hemorrhagic cystitis and the second for the treatment of adenovirus infection - both after allogeneic hematopoietic cell transplant. Likewise, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. Despite the results reported in earlier preclinical studies or clinical trials for our product candidates, to date, results may not be replicated in subsequent trials, and, should we resume development of our product candidates, we do not know whether any future clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market posoleucel, ALVR106 or any future product candidates we develop from our allogeneic T cell immunotherapy platform. Additionally, certain of our clinical trial endpoints also may not be adequately powered in a particular subpopulation of our trial population. Additionally, several of our clinical trials to date have been open-label trials. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to

an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

Efficacy data from prospectively designed trial may differ significantly from those obtained from retrospective subgroup analyses. In addition, clinical data obtained from a clinical trial with an allogeneic product candidate such as posoleucel may not yield the same or better results as compared to an autologous product candidate. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in such studies nonetheless failed to obtain FDA, EMA or other necessary regulatory agency approval.

If later-stage clinical trials do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates will be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, no cell-based therapies for the treatment of viral diseases have been approved to date, and the FDA or other regulatory authorities may not agree and may require that we conduct additional clinical trials to support the regulatory approval of our product candidates. If we fail to obtain results in our planned and future preclinical and clinical activities and studies sufficient to meet the requirements of the relevant regulatory agencies, the development timeline and regulatory approval and commercialization prospects for any potential product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected.

Interim, "topline" or preliminary data from our clinical trials that we may announce or share with regulatory authorities 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 announce or share with regulatory authorities interim, "topline" or preliminary data from our clinical trials based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. 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. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. Preliminary or "topline" 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 announced. As a result, interim, "topline," and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary, "topline," or interim data and final data could impact the regulatory approval of, and significantly harm the prospects for any product candidate that is impacted by the applicable data.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our business in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, "topline," or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize our product candidates, our business, operating results, prospects or financial condition may be harmed.

Our product candidates, the methods used to deliver them or their dosage levels may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following any regulatory approval.

Undesirable side effects caused by our product candidates, their delivery methods or dosage levels 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 authority. As a result of safety or toxicity issues that we may experience in our clinical trials, we may not receive approval to market any product candidates, which could prevent us from ever generating revenues or achieving profitability. Results of our trials could reveal an unacceptably high severity and incidence of side effects, or side effects outweighing the benefits of our product candidates. In such an event, our studies could be delayed, suspended or terminated and the

FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, while we note the summary of safety findings we have gathered, to date, certain populations of patients receiving our product candidates may experience side effects in greater frequency or severity than others who may receive our product candidates and additional clinical research is planned to more fully understand the safety profile of our product candidates in our patient populations and indications of focus.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or decide to remove the product form the marketplace;
- regulatory authorities may withdraw or change their approvals of that product;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;
- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

Should we resume development of our product candidates, we may not be able to obtain or maintain orphan drug designation to our product candidates, or to obtain and maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. The FDA has granted orphan drug designation to posoleucel for the treatment of virus-associated hemorrhagic cystitis. In the European Union, the prevalence of the condition must not be more than 5 in 10,000. The EMA has granted posoleucel orphan drug designation to treatment in HCT. This designation covers the treatment of all viruses targeted by posoleucel in all HCT patients: BK virus, or BKV, cytomegalovirus, or CMV, adenovirus, or AdV, Epstein-Barr virus, or EBV, and human herpesvirus 6, or HHV-6. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

If a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for a particular active ingredient 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 for the same indication, for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated. Even if we or our collaborators obtain orphan designation to a product candidate, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. The scope of exclusivity is limited to the scope of any approved indication, even if the scope of the orphan designation is broader than the approved indication. Additionally, exclusive marketing rights may be limited if we or our collaborators 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 the manufacturer is unable to assure sufficient

quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if a product obtains orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a product with the same active moiety for the same condition if the FDA concludes that the later product is safer, more effective, or makes a major contribution to patient care. Furthermore, the FDA can waive orphan exclusivity if we or our collaborators are unable to manufacture sufficient supply of the product. The FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Similarly, in Europe, a medicinal product may receive orphan designation under Article 3 of Regulation (EC) 141/2000. This applies to products that are intended for a life-threatening or chronically debilitating condition and either (1) such condition affects no more than five in 10,000 persons in the EU when the application is made, or (2) the product, without the benefits derived from orphan status, would be unlikely to generate sufficient returns in the EU to justify the necessary investment. Moreover, in order to obtain orphan designation in the EU it is necessary to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU or, if such a method exists, the product will be of significant benefit to those affected by the condition. In the EU, orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and applicants can benefit from specific regulatory assistance and scientific advice. Products receiving orphan designation in the EU can receive 10 years of market exclusivity, during which time no similar medicinal product for the same indication may be placed on the market. An orphan product can also obtain an additional two years of market exclusivity in the EU for pediatric studies. However, the 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation—for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the first applicant consents to a second orphan medicinal product application; or
- the first applicant cannot supply enough orphan medicinal product.

Should we resume development of our product candidates, if we or our collaborators do not receive or maintain orphan drug designation to product candidates for which we seek such designation, it could limit our ability to realize revenues from such product candidates.

Risks Related to Our Business and Commercialization

Risks Related to Sales, Marketing and Competition

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

We face competition from numerous pharmaceutical and biotechnology enterprises, as well as from academic institutions, government agencies and private and public research institutions. Our commercial opportunities will be significantly impacted if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are less expensive or obtain more significant acceptance in the market than any product candidates that we develop. Additionally, our commercial opportunities will be significantly impacted if novel upstream products or changes in treatment protocols reduce the overall incidence or prevalence of diseases in our current or future target population. Competition could result in reduced sales and pricing pressure on our product candidates, if approved by applicable regulatory authorities. In addition, significant delays in the development of our product candidates could allow our competitors to bring products to market before us and impair any ability to commercialize our product candidates.

While there are currently no FDA- or EMA-approved drugs for our indications (other than for COVID-19), many of the approved or commonly used drugs and therapies for our current or future target diseases, including letermovir, cidofovir, ganciclovir, valganciclovir, foscarnet, oseltamivir, zanamivir, baloxavir, ribavirin, tenofovir, and entecavir, are well established and are widely accepted by physicians, patients and third-party payors. Some of these drugs are branded and subject to patent protection, and other drugs and nutritional supplements are available on a generic basis. Insurers and other third-party payors may encourage the use of generic products or specific branded products. We expect that, if any of our product candidates are approved, they will be priced at a significant premium over competitive generic products. Absent differentiated and compelling clinical evidence, pricing premiums may impede the adoption of our products over currently approved or commonly used therapies, which may adversely impact our business. In addition, many companies are developing new therapeutics, and we cannot predict what the standard of care will become as our products continue in clinical development.

Many of our competitors or potential competitors have significantly greater market presence, financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical studies, obtaining regulatory approvals and marketing approved products than we do, and as a result may have a competitive advantage over us. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements or mergers with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific, commercial and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies and technology licenses complementary to our programs or advantageous to our business.

As a result of these factors, these competitors may obtain regulatory approval of their products before we are able to, which will limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are safer, more effective, more widely used and cheaper than ours, and may also be more successful than us in manufacturing and marketing their products. These appreciable advantages could render our product candidates obsolete or noncompetitive before we can recover the expenses of development and commercialization.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenue.

We are at any early stage of establishing an organization that will be responsible for the sale, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved by the FDA and comparable foreign regulatory authorities, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. There are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may be competing with many companies that currently have extensive and well-funded sales and marketing operations. Without a sufficiently scaled, appropriately timed and trained internal commercial organization or the support of a third party to perform sales and marketing functions, we may be unable to compete successfully against these more established companies.

The incidence and prevalence of the target patient population for posoleucel are based on estimates and third-party sources. If the market opportunity for posoleucel or our other product candidates is smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability might be materially and adversely affected.

Periodically, we make estimates regarding the incidence and prevalence of target patient populations based on various third-party sources and internally generated analysis. These estimates may be inaccurate or based on imprecise data. For example, the total addressable market opportunity for posoleucel will depend on, among other things, acceptance of posoleucel by the medical community and patient access, drug pricing and reimbursement. The number of patients in the addressable markets may turn out to be lower than expected, patients may not be otherwise amenable to treatment with posoleucel, or new patients may become increasingly difficult to identify or gain access to, all of which may significantly harm our business, financial condition, results of operations and prospects.

We have received Regenerative Medicine Advanced Therapy, or RMAT, designation for the treatment of HC caused by BKV in adults and children following allogeneic HCT , adenovirus (AdV) infection following allogenic hematopoietic stem cell transplant (allo-HCT) and for the prevention of clinically significant infections and disease from six devastating viruses that commonly impact high-risk adult and pediatric patients following allo-HCT – adenovirus (AdV), BK virus (BKV), cytomegalovirus (CMV), Epstein-Barr virus (EBV), human herpes virus-6 (HHV-6) and JC virus (JCV), and received eligibility for the PRIME scheme from the EMA for the treatment of serious infections with BKV, CMV, AdV, EBV and HHV-6 in HCT patients, for posoleucel. These designations may not lead to a faster development or regulatory review or approval process, and will not increase the likelihood that such product candidates will receive marketing approval.

We have received RMAT designation from the FDA for posoleucel for the treatment of HC caused by BKV in adults and children following allo-HCT, for the treatment of AdV infection following allo-HCT, and for the prevention of clinically significant infections and end-organ diseases from AdV, BKV, CMV, EBV, HHV-6 and JCV in children and adults following allo-HCT. We have also received PRIME designation from the EMA for the treatment of serious infections with BKV, CMV, AdV, EBV and/or HHV-6 in HCT patients.

A company may request RMAT designation of its product candidate, which designation may be granted if the product meets the following criteria: (1) it is 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 potential 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 post-approval, if appropriate. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements 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 data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy. Under the Food and Drug Omnibus Reform Act of 2022 (FDORA), the FDA is permitted to require, as appropriate, that a post-approval confirmatory study or studies be underway prior to approval or within a specified time period after the date of approval for a product granted accelerated approval. FDORA also requires sponsors to send updates to the FDA every 180 days on the status of such studies, including progress toward enrollment targets, and the FDA must promptly post this information publicly. FDORA also gives the FDA increased authority to withdraw approval of a drug or biologic granted accelerated approval on an expedited basis if the sponsor fails to conduct such studies in a timely manner, send the necessary updates to the FDA, or if such post-approval studies fail to verify the drug's predicted clinical benefit. Under FDORA, the FDA is empowered to take action, such as issuing fines, against companies that fail to conduct with due diligence any post-approval confirmatory study or submit timely reports to the agency on their progress. In addition, for products being considered for accelerated approval, the FDA generally requires, unless otherwise informed by the agency, that all advertising and promotional materials intended for dissemination or publication within 120 days of marketing approval be submitted to the agency for review during the pre-approval review period. There can be no assurance that the FDA would allow any of the product candidates we may develop to proceed on an accelerated approval pathway, and even if the FDA did allow such pathway, there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. Moreover, even if we received accelerated approval, any post-approval studies required to confirm and verify clinical benefit may not show such benefit, which could lead to withdrawal of any approvals we have obtained. Receiving accelerated approval does not assure that the product's accelerated approval will eventually be converted to a traditional approval.

PRIME is a scheme provided by the EMA to enhance support for the development of medicines that target an unmet medical need. To qualify for PRIME, product candidates require early clinical evidence that the therapy has the potential to offer a therapeutic advantage over existing treatments or benefits patients without treatment options. Among the benefits of PRIME are the appointment of a rapporteur to provide continuous support and help build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

RMAT designation and PRIME eligibility do not change the standards for product approval, and there is no assurance that any such designation or eligibility will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation or PRIME eligibility. Additionally, RMAT designation and access to PRIME can each be revoked if the criteria for eligibility cease to be met as clinical data emerges.

Even if our product candidates receive regulatory approval, we will still face extensive ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense, and our products may still face future development and regulatory difficulties.

Even if we obtain regulatory approval for a product candidate, it would be subject to ongoing requirements by the FDA and comparable foreign regulatory authorities governing the manufacture, materials and facilities, qualification testing, quality control, further development, labeling, packaging, storage, distribution, post-approval clinical data, adverse event reporting, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting of safety and other post-marketing information. These requirements include submissions of safety and other post-marketing information and reports, establishment registration and product listing, as well as continued compliance by us and/or our contract manufacturing organizations, or CMOs, and CROs for any post-approval clinical trials that we conduct. The safety profile of any product will continue to be closely monitored by the FDA and comparable foreign regulatory authorities after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of our product candidates, they may require labeling changes or establishment of a REMS, impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance.

In addition, manufacturers of drug products and their facilities are subject to initial and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with current good manufacturing practices, or cGMP, Good Clinical Practices, or GCP, current good tissue practices, or CGTP, and other regulations. For certain commercial prescription biological products, manufacturers, and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates

or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners, or require other restrictions on the labeling or marketing of such products;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend, withdraw or modify regulatory approval;
- suspend or modify any ongoing clinical trials;
- refuse to approve pending applications or supplements to applications filed by us;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products, refuse to permit the import or export of products, or require us to initiate a product recall.

The occurrence of any event or penalty described above may inhibit our ability to successfully commercialize our products.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, the Department of Justice, or the DOJ, the Office of Inspector General of the HHS, state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to corrective information to healthcare practitioners, injunctions, or civil or criminal penalties.

The FDA and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of any current or future product candidate. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or to 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. Non-compliance by us or any future collaborator with regulatory requirements, including safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population can also result in significant financial penalties.

Regulations, guidelines and recommendations published by various government agencies and organizations may affect the use of our product candidates.

Changes to regulations, recommendations or other guidelines advocating alternative therapies for the indications we treat could result in decreased use of our products, if approved.

Risks Related to Business Development and Commercialization

We may not successfully identify, acquire, develop or commercialize new potential product candidates.

Part of our business strategy is to expand our product candidate pipeline by identifying and validating new product candidates, which we may develop ourselves, in-license or otherwise acquire from others. In addition, in the event that our existing product candidates do not receive regulatory approval or are not successfully commercialized, then the success of our business will depend on our ability to expand our product pipeline through in-licensing or other acquisitions. We may be unable to identify relevant product candidates. If we do identify such product candidates, we may be unable to reach acceptable terms with any third party from which we desire to in-license or acquire them.

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, patients, healthcare payors and the medical community, including hospitals and outpatient clinics.

Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics. Market acceptance of any of our product candidates for which we receive approval depends on a number of factors, including:

- the efficacy and safety of the product candidates as demonstrated in clinical trials;
- the clinical indications and patient populations for which the product candidate is approved;
- acceptance by physicians and patients of the drug as a safe and effective treatment;
- the administrative and logistical burden of treating patients, including the availability and accessibility of healthcare provider sites for administering infusions to patients;
- the adoption of novel cellular therapies by physicians, hospitals and third-party payors;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- any restrictions on use together with other medications;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- the timing of market introduction of our products as well as competitive products;
- the development of manufacturing and distribution processes for our product candidates;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement from, and our ability to negotiate pricing with, third-party payors, providers and government authorities;
- relative convenience and ease of administration; and
- the effectiveness of our sales and marketing efforts and those of our collaborators.

Even if we are able to commercialize our product candidates, the products may not receive coverage and adequate reimbursement from third-party payors in the United States and in other countries in which we seek to commercialize our products, which could harm our business.

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to commercialize any product successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. For more information regarding the risks related to insurance coverage and reimbursement please see "*Business – Government Regulation – Coverage and Reimbursement*."

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, determine which medications they will cover and establish reimbursement levels. A primary trend in the healthcare industry is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Third-party payors may also seek additional clinical evidence, beyond the data required to obtain regulatory approval, demonstrating clinical benefits and value in specific patient populations before covering our products for those patients. We cannot be sure that coverage and adequate reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Coverage

and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain regulatory approval, and ultimately our ability to successfully commercialize any product candidate for which we obtain regulatory approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may only be temporary. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. Third-party payors in the U.S. often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We must complete clinical testing before we can seek regulatory approval and begin commercialization of any of our product candidates.

There is no guarantee that any of our product candidates will proceed in preclinical or clinical development or achieve regulatory approval. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned or, if at all.

There is no guarantee that the results obtained in current clinical studies or planned Phase 3 clinical trials of posoleucel will be sufficient to obtain regulatory approval or marketing authorization for HC, AdV, prevention or any other indication. Negative results in the development of our lead product candidates may also impact our ability to obtain regulatory approval for our other product candidates, either at all or within anticipated timeframes because, although other product candidates may target different indications, the underlying technology platform, manufacturing process and development process is the same for all of our product candidates. Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other product candidates.

In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our lead product candidates, we may forgo or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate, we may relinquish valuable rights to those future product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates.

Current and future legislation, including potentially unfavorable pricing regulations or other healthcare reform initiatives, may increase the difficulty and cost for us to obtain regulatory approval of and commercialize our product candidates and affect the prices we may obtain.

The regulations that govern, among other things, regulatory approvals, coverage, pricing and reimbursement for new drug products vary widely from country to country. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post-approval activities and affect our ability to successfully sell any product candidates for which we obtain regulatory approval. The U.S. government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-‒paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs. Additional changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges and fraud and abuse and enforcement. Continued implementation of the Affordable Care Act, or ACA, and the passage of additional laws and regulations may result in the expansion of new programs, such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the

physician quality reporting system and feedback program. For more information regarding the risks related to recently enacted and future legislation please see "*Business – Government Regulation – Healthcare Reform*."

We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare drugs and services, which could result in reduced demand for our drug candidates or additional pricing pressures. 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 approved 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.

Individual states in the U.S. have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our drugs or put pressure on our drug pricing, which could negatively affect our business, financial condition, results of operations and prospects.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of regulatory approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we, or our collaborators, may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

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

The Biologics Price Competition and Innovation Act of 2009, or 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 processes intended to implement BPCIA may be fully adopted by the FDA, any of these 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.

In addition, the approval of a biologic product biosimilar to one of our products could have a material adverse impact on our business as it may be significantly less costly to bring to market and may be priced significantly lower than our products.

Our relationships with customers, third-party payors, physicians and healthcare providers will be subject to applicable anti-kickback, fraud and abuse, and other laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, and diminished profits.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any product candidates for which we obtain regulatory approval. Our current and future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we conduct research and would market, sell and distribute our products. As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. For more information regarding the risks related to these laws and regulations please see "Business – Government Regulation – Other Healthcare Laws and Compliance Requirements."

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Even if precautions are taken, it is possible that governmental authorities will conclude that our business practices could, despite efforts to comply, be subject to challenge under current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect our business in an adverse way.

Efforts to ensure that our current and future business arrangements with third parties, and our business generally, continue to comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with any such laws and regulations. If our operations, including our arrangements with physicians and other healthcare providers, are found to be in violation of any such laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, reputational harm, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, disgorgement, additional reporting requirements, and/or the curtailment or restructuring of our operations, as well as additional reporting obligations oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. If any physicians or other healthcare providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to similar penalties.

Changes in and failures to comply with U.S. federal and state and foreign privacy and data protection laws, regulations and standards may adversely affect our business, operations and financial performance.

In the United States, HIPAA, as amended by HITECH, imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, received, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, or the FTCA, 15 U.S.C. § 45(a).

In addition, certain states have enacted or proposed comprehensive consumer privacy legislation, such as the CCPA, to govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the CCPA created comprehensive individual privacy rights for California consumers (as defined in the law) and placed increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA and similar comprehensive state consumer privacy laws, both proposed and enacted, could increase our potential liability and adversely affect our

business. We will continue to monitor developments related to the CCPA, as amended by the CPRA, as well as other recently enacted comprehensive state consumer privacy laws, for which we anticipate additional costs and expenses associated with compliance.

We may also be subject to additional privacy restrictions in various foreign jurisdictions around the world in which we operate or process personal information. The collection, use, storage, disclosure, transfer, or other processing of personal information regarding individuals in the European Economic Area, or EEA, including personal health data, is subject to the General Data Protection Regulation 2016/679, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the European Union, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In addition, various other jurisdictions around the world continue to propose new and/or amended laws that regulate the privacy and/or security of certain types of personal data. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines and penalties if we are unable to comply.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems for specific use cases reviewed by legal and information security. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

We are highly dependent on our key personnel and anticipate hiring new key personnel. 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 David Hallal, our Chairman and former Chief Executive Officer, Diana Brainard, our Chief Executive Officer, Vikas Sinha, our President and Chief Financial Officer, and Ann Leen, our Chief Scientific Officer. While we expect to engage in an orderly transition process as we integrate newly appointed officers and managers, such as Diana Brainard who was appointed Chief Executive Officer effective May 17, 2021, we face a variety of risks and uncertainties relating to management transition, including diversion of management attention from business concerns, failure to retain other key personnel or loss of institutional knowledge. In addition, the loss of the services of any of our executive officers, other key employees and other scientific and medical advisors, and an inability to find suitable replacements could result in delays in product development and harm our business. For example, Dr. Leen is a Professor at Baylor College of Medicine and is also a co-founder of Marker Therapeutics. There could be a diversion of attention with

an increased focus on her other service obligations and such a loss of her services to us could result in delays of our product development and impact our operations. Additionally, some of our executive officers, directors and other personnel split their time between AlloVir and ElevateBio. For instance, David Hallal serves as Chief Executive Officer of ElevateBio and Chairman of both AlloVir and ElevateBio, and Vikas Sinha serves as Chief Financial Officer of both AlloVir and ElevateBio. As a result, these individuals may not be able to devote their full attention to us, which could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy.

We conduct our operations at our facilities in Waltham, Massachusetts and Dublin, Ireland. Each of those regions serve as 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. Changes to U.S. immigration and work authorization laws and regulations, including those that restrain the flow of scientific and professional talent, can be significantly affected by political forces and levels of economic activity. Our business may be materially adversely affected if legislative or administrative changes to immigration or visa laws and regulations impair our hiring processes and goals or projects involving personnel who are not U.S. citizens.

To encourage valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock options that vest over time and offer an employee stock purchase plan. The value to employees of restricted stock and stock options that vest over time, as well as shares purchased through an employee stock purchase plan, 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. 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.

Certain of our directors and officers may have actual or potential conflicts of interest because of their positions with ElevateBio.

David Hallal, our Executive Chairman and former Chief Executive Officer, also serves as the Chairman and Chief Executive Officer of ElevateBio, and Vikas Sinha, our President and Chief Financial Officer, also serves as the Chief Financial Officer of ElevateBio. Morana Jovan-Embiricos, a member of our board of directors, also serves as a director of the board of directors of ElevateBio. In addition, certain of these individuals own equity interests in ElevateBio, which may represent a significant portion of these individuals' net worth. Although, we have adopted a written related party transactions policy that such transactions must be approved by our audit committee, their positions at ElevateBio and the ownership of any ElevateBio equity or equity awards creates, or may create the appearance of, conflicts of interest when we ask these individuals to make decisions that could have different implications for ElevateBio than the decisions have for us.

Should we resume development of our product candidates, we may need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of December 31, 2023, we had 112 employees. If we resume development of our product candidates, our development and commercialization plans and strategies develop, and as we continue to operate as a public company, we would expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including:

- managing our preclinical studies and clinical trials effectively;
- identifying, recruiting, maintaining, motivating and integrating additional employees;
- managing our internal development efforts effectively while complying with our contractual obligations to licensors, licensees, contractors and other third parties;
- improving our managerial, development, operational, information technology, and finance systems; and
- expanding our facilities.

Should we resume development of our product candidates, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and any preclinical or clinical studies effectively and hire, train and integrate additional management, research and development, manufacturing, administrative and sales and marketing personnel. Our failure to accomplish any of these tasks could prevent us from successfully achieving our research, development and commercialization goals.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee and third party misconduct, and the precautions we take to detect and prevent this activity 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. 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 and results of operations, including the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

Risks Related to our Business

We may be unable to adequately protect our information systems from cyber attacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our platform and product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state law, such as state breach notification laws, federal law, such as HIPAA, as amended by HITECH, and international law, such as the GDPR and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

In addition, the computer systems of various third parties on which we rely, including our CROs and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third-party providers to implement effective security measures and identify and correct any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Our internal computer systems, or those used by our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of the development programs of our product candidates.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, and telecommunication and electrical failures. We exercise little or no control over these third parties, which increases our vulnerability to problems with their systems. 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 data from completed or future preclinical studies and clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. 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 and our business could be otherwise adversely affected.

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

Our operations, and those of our CROs, CMOs 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, the severity and frequency of which may be amplified by global climate change, could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption.

Changes in U.S. or foreign tax law or changes in our effective tax rates could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation and foreign income taxation are constantly under review by persons involved in the legislative process, by the Internal Revenue Service, the U.S. Treasury Department and foreign tax authorities. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. For example, under Section 174 of the Code, in taxable years beginning after December 31, 2021, expenses that are incurred for research and development in the U.S. are now capitalized and amortized, which may have an adverse effect on our future cash flows. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future.

For example, the Tax Cuts and Jobs Act, or the TCJA, was enacted in 2017 and made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, the limitation of the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), and, subject to certain changes in tax law made by the CARES Act as discussed below, the limitation of the deduction for net operating losses from taxable years beginning after December 31, 2017 to 80% of current year taxable income and the elimination of net operating loss carrybacks generated in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. In addition, on March 27, 2020, President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security Act" or the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters.

It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

We are subject to tax in both U.S. and foreign jurisdictions and determining our worldwide tax liabilities is complex and requires significant judgment. We could incur additional tax liability if relevant tax authorities disagree with our reported tax positions. Our effective tax rate could be adversely affected by changes in the mix of earnings in countries with different statutory tax rates, challenges to our transfer pricing practices, changes in the valuation of deferred tax assets and liabilities, changes in tax laws and regulations, and changes in our tax filings due to tax audits.

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

Our ability to use our U.S. federal, U.S. state and foreign net operating losses to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our net operating losses.

Unused U.S. federal tax losses for tax years beginning before January 1, 2018 and prior tax years will carry forward to offset future taxable income, if any, until such unused losses expire. Unused U.S. federal tax losses generated for tax year beginning after December 31, 2017 will not expire and may be carried forward indefinitely, and generally may not be carried back to prior taxable years, except that, under the CARES Act, net operating losses generated in 2018, 2019 and 2020 may be carried back to each of the five tax years preceding the tax years of such losses. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such U.S. federal net operating losses is limited to 80% of our taxable income in any future taxable year. In addition, both our current and our future unused U.S. federal and state tax losses and unused U.S. federal and state research and development tax credits may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a rolling three-year period. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2023, we reported U.S. federal and state net operating loss carryforwards of approximately $38.9 million and $26.4 million, respectively, federal and state research and development tax credit carryforwards of $11.7 million and $2.1 million, respectively, and federal orphan drug credit carryforwards of $6.0 million. Our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to us.

As of December 31, 2023, we reported foreign net operating loss carryforwards of $354.8 million. Our ability to utilize those net operating loss carryforwards are dependent upon our generation of future taxable income

Unstable market, economic or geopolitical conditions may have serious adverse consequences on our business, financial condition and stock price.

Global credit and financial markets have experienced and are likely to continue to experience extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest rates, 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. Further, geopolitical instability outside the U.S. may also impact our operations or affect global markets, such as the recent invasion of Ukraine by Russia. While we do not currently conduct clinical trials in the Ukraine or Russia, we cannot be certain what the overall impact of these events will be on our business or on the business of any of our third party partners, including our CROs, contract manufacturers or other partners or on the health care systems in the European Union and in other impacted countries. 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, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn

amounts thereunder. Although we are not a borrower or party to any such instruments with SVB, Signature or any other financial institution currently in receivership, if any of our suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to perform their obligations to us or to enter into new commercial arrangements could be adversely affected. Additionally, if any financial institution where we have deposits is put into receivership, access to our deposits could be delayed and uninsured deposits could be lost, either of which could have a material and adverse impact on our current and projected business operations and our financial condition.

Risks Related to Litigation

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. On January 19, 2024, a purported stockholder of the Company filed a putative class action lawsuit against the Company and certain of our officers in federal court in Massachusetts, alleging that the Company violated the federal securities laws by making allegedly false and misleading statements and omissions relating to our Phase 3 posoleucel trials (see Item 3, Legal Proceedings, for additional details regarding this lawsuit). This lawsuit, and other similar lawsuits that may follow, could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical studies and will face an even greater risk if we commercially sell any products that we may develop. Product liability claims may be brought against us by subjects enrolled in our clinical studies, patients, healthcare providers or others using, administering or selling our products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- termination of clinical trial sites or entire trial programs;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to study subjects or patients;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- diversion of management and scientific resources from our business operations;
- the inability to commercialize any products that we may develop; and
- a decline in our share price.

We currently hold product liability insurance coverage at a level that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, but which may not be adequate to cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain regulatory approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products that receive regulatory approval. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us, particularly if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Risks Related to Intellectual Property Litigation

If we are sued for infringing the intellectual property rights of third parties, the resulting litigation could be costly and time-consuming and could prevent or delay our development and commercialization efforts.

Our commercial success depends, in part, on us and our partners, including BCM, not infringing the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. There is a substantial amount of litigation and other adversarial proceedings, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interference or derivation proceedings, oppositions, reexaminations, and *inter partes* and post-grant review proceedings before the USPTO and non-U.S. patent offices. Numerous U.S. and non-U.S. issued patents and pending patent applications owned by third parties exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of third parties' patent rights, as it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform or predictable. In addition, many companies in intellectual property-dependent industries, including the biotechnology and pharmaceutical industries, have employed intellectual property litigation as a means to gain an advantage over their competitors. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

Third parties may assert infringement claims against us based on existing or future intellectual property rights, alleging that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacturing of our product candidates that we failed to identify. For example, patent applications covering our product candidates could have been filed by others without our knowledge, since these applications generally remain confidential for some period of time after their filing date. Even pending patent applications that have been published, including some of which we are aware, could be later amended in a manner that could cover our product candidates or their use or manufacture. After issuance, the scope of patent claims remains subject to construction as determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. In addition, we may have analyzed patents or patent applications of third parties that we believe are relevant to our activities and believe that we are free to operate in relation to any of our product candidates, but our competitors may obtain issued claims, including in patents we consider to be unrelated, which may block our efforts or potentially result in any of our product candidates or our activities infringing their claims.

If we or our partners, including BCM, are sued for patent infringement, we would need to demonstrate that our product candidates, products and methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving that a patent is invalid or unenforceable is difficult and even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. If any issued third-party patents were held by a court of competent jurisdiction to be valid and enforceable and cover aspects of our materials, formulations, methods of manufacture or methods for treatment, we could be forced, including by court order, to cease developing, manufacturing or commercializing the relevant product candidate until the relevant patent expires. Alternatively, we may desire or be required to obtain a license from such third party in order to use the infringing technology and to continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonably terms, or at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property licensed to us. Additionally, in the event of a successful intellectual property claim against us, we may have to pay substantial damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent, or to redesign our infringing product candidates, which may be impossible or technically infeasible, or require substantial time and monetary expenditure. In addition to paying monetary damages, we may lose valuable intellectual property rights or personnel and the parties making claims against us may obtain injunctive or other equitable relief, which could impose limitations on the conduct of our business.

We may face claims that we misappropriated the confidential information or trade secrets of a third party. If we are found to have misappropriated a third party's trade secrets, we may be prevented from further using these trade secrets, which could limit our ability to develop our product candidates.

Defending against intellectual property claims could be costly and time consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle before a final judgment, any litigation could burden us with substantial unanticipated costs. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. During the course of any intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation and these announcements may have negative impact on the perceived value of our product candidates, programs or intellectual property. Any uncertainties resulting from the initiation and continuation of any litigation could have material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. As a result of all of the foregoing, any actual or threatened intellectual property claim could prevent us from developing or commercializing a product candidate or force us to cease some aspect of our business operations.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. Our patent applications cannot be enforced against third parties practicing the technology claimed in these applications unless and until a patent issues from the applications, and then only to the extent the issued claims cover the technology. In the future, we or our partners may elect to initiate legal proceedings to enforce or defend our or our partners' intellectual property rights, to protect our or our partners' trade secrets or to determine the validity, ownership, enforceability or scope of our intellectual property rights. Any claims that we or our partners assert against perceived infringers could also provoke these parties to assert counterclaims against us or our partners alleging that we or our partners infringe their intellectual property rights or that our intellectual property rights are invalid or unenforceable.

Interference or derivation proceedings provoked by third parties, brought by us or our partners, or declared by the USPTO may be necessary to determine the priority of inventions or matters of inventorship with respect to our patents or patent applications. We or our partners may also become involved in other proceedings, such as reexamination or opposition proceedings, *inter partes* review, post-grant review or other pre-issuance or post-grant proceedings before the USPTO or in non-U.S. jurisdictions relating to our intellectual property or the intellectual property of others. An unfavorable outcome in any of these proceedings could result in us losing our valuable intellectual property rights, require us or our partners to cease using the related technology and commercializing our product candidates, or require us to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us or our partners a license on commercially reasonable terms if any license is offered at all. Even if we or our licensors obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us or our partners. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Any intellectual property proceedings can be expensive and time-consuming. Our or our partners' adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we or our partners can. Accordingly, despite our or our partners' efforts, we or our partners may not be able to prevent third parties from infringing upon or misappropriating our intellectual property rights, particularly in countries where the laws may not protect our rights as fully as in the U.S. Even if we are successful in the relevant proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted from other activities. In addition, in an infringement proceeding, a court may decide that one or more of our patents is invalid or unenforceable, in whole or in part, 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 proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

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, and if securities analysts or investors view these announcements in a negative light, the price of our common stock could be adversely affected.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Risks Related to Our Financial Condition, Capital Needs and Ownership of Our Common Stock

Risks Related to Financial Condition

We are a clinical-stage cell therapy company and we have incurred net losses since our inception. We anticipate that we will continue to incur significant losses for the foreseeable future, and may never achieve or maintain profitability.

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 effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We 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 clinical development and ongoing operations. As a result, we are not profitable and have incurred losses in each period since our inception. Since our inception, we have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and our clinical trials. Our financial condition and operating results, including net losses, may fluctuate significantly from quarter to quarter and year to year. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance. Additionally, net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our net losses were $190.4 million and $168.7 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $656.2 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

We anticipate that our expenses will increase substantially if and as we:

- resume clinical trials for our lead product candidate, posoleucel, for our initial and potential additional indications;
- initiate and continue research, preclinical and clinical development efforts for our additional product candidates, including ALVR106 and ALVR107 and any future product candidates we may develop;
- seek to identify additional product candidates;
- seek regulatory approvals for posoleucel or any other product candidates that successfully complete clinical development, should we resume development of our product candidates;
- add operational, financial and management information systems and personnel, including personnel to help us comply with our obligations as a public company;
- hire and retain additional personnel, such as clinical, quality control, scientific, commercial and administrative personnel, to support our product candidate development;
- maintain, expand and protect our intellectual property portfolio;
- establish sales, marketing, distribution, manufacturing, supply chain and other commercial infrastructure in the future to commercialize any product candidates for which we may obtain regulatory approval;
- add equipment and physical infrastructure to support our research and development; and
- acquire or in-license other product candidates and technologies.

Our expenses could increase beyond our expectations if we are required by the FDA or other regulatory authorities to perform clinical trials in addition to those that we currently expect, if there are any delays in establishing appropriate manufacturing arrangements for our product candidates, or if we experience delays in the completion of our clinical trials or the development of any of our product candidates for any reason.

We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability.

Our company was formed in August 2013. Since inception, we have devoted substantially all of our resources on raising capital, organizing and staffing our company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing posoleucel, ALVR106, and other product candidates and preparing for clinical trials and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. We have financed our operations primarily through private placements of our preferred stock, our initial public offering, or IPO, in August 2020, our registered direct offering in July 2022 and our public offering in June 2023. We have not yet demonstrated our ability to successfully complete any Phase 3 clinical trials, obtain regulatory approval, consistently manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for the successful commercialization of any of our product candidates. In addition, the allogeneic, off-the-shelf, multi-virus specific T approach of our cell therapies is new and largely unproven. Any predictions about our future success, performance or viability, particularly in view of the rapidly evolving immunotherapy field, may not be accurate given our limited operating history and lack of approved products.

In addition, given our limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities and may not be successful in such a transition. We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, our financial results for any quarterly or annual periods may not be indicative of future operating performance.

Risks Related to Capital Needs

We will need substantial additional funding, and if we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product discovery and development programs or commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Should we resume development of our product candidates, we would expect to spend substantial amounts of capital on the preclinical and clinical development of our current and future programs. If we are able to gain marketing approval for any product candidate we develop, including for any indication for which we are developing or may develop posoleucel, we will require substantial additional funding in order to launch and commercialize such product candidates, to the extent that such launch and commercialization are not the responsibility of a collaborator that we may contract with in the future. In addition, other unanticipated costs may arise in the course of our development efforts. Under the terms of our license agreements with each of our partners, including BCM, we are obligated to make payments upon the achievement of certain development, regulatory and commercial milestones. Because the design and outcome of our planned and anticipated clinical trials is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. Additionally, any delays due to changes in federal, state, or local laws and regulations or clinical site policies could impact the timing and cost of the development of our product candidates.

Should we resume the development of our product candidates, our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing posoleucel for our initial and potential additional indications, as well as ALVR106 and other product candidates we may develop, including other effects on our development programs;
- the timing of, and the costs involved in, developing manufacturing and distribution processes and obtaining marketing approvals for posoleucel for our initial and potential additional indications, and ALVR106 other product candidates we may develop;
- if approved, the costs of commercialization activities for posoleucel for any approved indications, or ALVR106 or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of a collaborator that we may contract with in the future, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of posoleucel for any approved indications or ALVR106 or any other product candidates;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs as we expand our research and development, increase our office space, and establish a commercial infrastructure;

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

We had cash, cash equivalents and short-term investments of $183.9 million as of December 31, 2023. 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. Any of our current or future license agreements may also be terminated if we are unable to meet the payment or other obligations under the agreements.

We believe that our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements through at least twelve months following the issuance of these financial statements. This estimate may prove to be wrong, and we could use our available capital resources earlier than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds earlier than planned.

Risks Related to Manufacturing

We intend to develop an efficient and highly productive manufacturing supply chain for our allogeneic, off-the-shelf single- and multi-VST cell therapies. Delays in process performance qualification to validate the drug product manufacturing process could delay regulatory approvals, our development plans and thereby limit our ability to generate revenues.

If regulatory approvals for our CMOs are delayed, we may not be able to manufacture sufficient quantities of our drug candidates, which would limit our development activities and our opportunities for growth and revenues. In addition to the risks described in "Risks Related to Our Dependence on Third Parties," our existing CMOs, contract testing laboratory or existing raw material suppliers will be subject to ongoing, periodic inspection by the FDA, EMA or other comparable regulatory agencies to ensure compliance with cGMP and CGTP. Our or their failure to follow and document our adherence to these regulations or other regulatory requirements may lead to significant delays in the availability of products for clinical or, in the future, commercial use, may result in the termination of or a hold on a clinical trial, or may delay or prevent filing or approval of commercial marketing applications for our product candidates. We also may encounter problems with the following:

- achieving adequate or clinical-grade materials that meet regulatory agency standards or specifications with consistent and acceptable production yield and costs;
- shortages of qualified personnel, raw materials including cell culture media, peptides, cytokines or drug product formulation buffer or key contractors, including on account of the COVID-19 pandemic; and
- ongoing compliance with cGMP regulations and other requirements of the FDA, EMA or other comparable regulatory agencies.

Failure to comply with applicable regulations could also result in sanctions being imposed on us or our partners, including fines, injunctions, civil penalties, a requirement to suspend or put on hold one or more of our clinical trials, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates, operating restrictions and criminal prosecutions, any of which could harm our business.

Developing advanced manufacturing techniques and process controls is required to fully utilize our or our partner's facility. Without further investment, advances in manufacturing techniques may render our or our partner's facility and equipment inadequate or obsolete.

A number of our product candidates, if approved by applicable regulatory authorities, may require significant commercial supply to meet market demand. To meet such demand, we will need to increase, or "scale up," the production process by a significant factor over the initial level of production. If we are unable to do so, are delayed in doing so, or if the cost of this scale up is not economically feasible for us or we cannot find a third-party supplier, we may not be able to produce our product candidates in a sufficient quantity to meet future demand or at commercially feasible costs.

Risks Related to Third Party Manufacturing

We and our third-party partners are subject to a multitude of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

Concurrently with the license of our existing product candidates, we acquired manufacturing process know-how and, in some cases, inventory of process intermediates and clinical materials from our partners. Transferring manufacturing processes, testing and associated know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. Each stage is retroactively and concurrently verified to be compliant with appropriate regulations and to confirm that no changes have occurred that require the conduct of any bridging studies to maintain the validity of manufacturing data in support of our clinical product candidates or any future approved products. As a result, there is a risk that all relevant know-how was not adequately transferred to us from our partners or that previous execution was not compliant with applicable regulations.

In addition, we need to conduct significant development and scale-up work to transfer these processes and manufacture each of our product candidates for various studies, clinical trials and commercial launch readiness. To the extent we elect to transfer manufacturing within our network, we are required to demonstrate that the product manufactured in the new or "receiving" facility is comparable to the product manufactured in the original or "sending" facility. The inability to demonstrate to each of the applicable regulatory authorities that comparable drug product was manufactured could delay the development of our product candidates. Additionally, the manufacturing facilities in which our product candidates will be made could be adversely affected by earthquakes and other natural disasters, equipment failures, labor shortages, power failures, and numerous other factors.

The processes by which our product candidates are manufactured were initially developed by our partners for clinical purposes. We are advancing the existing processes to support advanced clinical studies and commercialization. Developing commercially viable cell therapy manufacturing processes is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical studies or commercialization, including cost overruns, potential problems with process scale-up, process reproducibility, process comparability, stability issues, consistency and timely availability of reagents or raw materials. The manufacturing facilities in which our product candidates will be made could be adversely affected by earthquakes and other natural disasters, equipment failures, labor shortages, power failures, and numerous other factors. In the case of highly innovative advanced therapy medicinal products (ATMP), reagents and raw materials of optimal pharmaceutical grade are not always available and, in those cases, health agencies must grant exemptions as part of the registration process. If such exemptions are not granted, regulatory approvals may be delayed until such time as these requirements are met.

The process of manufacturing cellular therapies is susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing and distribution processes for any of our product candidates could result in reduced production yields, impact to key product quality attributes, and other supply disruptions. Product defects can also occur unexpectedly. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, these manufacturing facilities may need to be closed for an extended period of time to allow us to investigate and remedy the contamination. Because our multi-VST cell therapy product candidates are manufactured from the blood of third-party donors, the process of manufacturing is susceptible to the availability of the third-party donor material. The process of developing products that can be commercialized may be particularly challenging, even if they otherwise prove to be safe and effective. The manufacture of these product candidates involves complex processes. Some of these processes require specialized equipment and highly skilled and trained personnel. The process of manufacturing these product candidates will be susceptible to additional risks, given the need to maintain aseptic conditions throughout the manufacturing process. Contamination with viruses or other pathogens in either the donor material or materials utilized in the manufacturing process or ingress of microbiological material at any point in the process may result in contaminated or unusable product. This type of contaminations could result in delays in the manufacture of products which could result in delays in the development of our product candidates. These contaminations could also increase the risk of adverse side effects. Furthermore, our allogeneic products ultimately consist of many individual cell lines, each with a different HLA profile. As a result, the selection and distribution of the appropriate cell line for therapeutic use in a patient requires close coordination between clinical operations, supply chain and quality assurance personnel.

Any adverse developments affecting manufacturing operations for our product candidates may result in lot failures, inventory shortages, shipment delays, product withdrawals or recalls or other interruptions in the supply of our drug product which could delay the development of our product candidates. We may also have to write off inventory, incur other charges and expenses for supply of drug product that fails to meet specifications, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Inability to meet the demand for our product candidates could damage our reputation and the reputation of our products among physicians, healthcare payors, patients or the medical community that supports our product development efforts, including hospitals and outpatient clinics.

Maintaining clinical and commercial timelines is dependent on our end-to-end supply chain network to support manufacturing; if we experience problems with our third party suppliers, the development and potential commercialization of our product candidates may be delayed.

We rely in part on our CMOs or our partners for the production of our product candidates and the acquisition of materials incorporated in or used in the manufacturing or testing of our product candidates. Our CMOs or partners are not our employees, and except for remedies available to us under our agreements with our CMOs or partners, we cannot directly control whether or not they devote sufficient time and resources, including experienced staff, to the manufacturing of supply for our ongoing preclinical studies and clinical trials.

Should we resume development of our product candidates, to meet our projected supply needs for clinical and commercial materials to support our activities through regulatory approval and commercial manufacturing of posoleucel and ALVR106 or any future product candidates resulting from our allogeneic T cell immunotherapy platform, we will need to transition the manufacturing of these materials to a CMO or our own facility. Regardless of where production occurs, we will need to develop relationships with suppliers of critical starting materials or reagents, increase the scale of production and demonstrate comparability of the material produced at these facilities to the material that was previously produced. Transferring manufacturing processes and know-how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We would expect additional comparability work will also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know-how and data has been adequately incorporated into the manufacturing process until the completion of studies and the related evaluations intended to demonstrate the comparability of material previously produced with that generated by our CMO.

If we are not able to successfully transfer and produce comparable product candidates, our ability to further develop and manufacture our product candidates may be negatively impacted.

While access to the ElevateBio manufacturing facility provides us with flexibility within our manufacturing network, we still may need to identify additional CMOs for continued production of supply for some of our product candidates. Given the nature of our manufacturing processes, the number of CMOs who possess the requisite skill and capability to manufacture our T cell immunotherapy product candidates is limited. We have identified a limited number of alternate suppliers in the event ElevateBio and the current CMOs that we utilize are unable to scale production, or if we otherwise experience any problems with them.

Manufacturing cellular therapies is complicated and tightly regulated by the FDA and comparable regulatory authorities around the world, and although alternative third-party suppliers with the necessary manufacturing and regulatory expertise and facilities exist, it could be expensive and take a significant amount of time to arrange for alternative suppliers, transfer manufacturing procedures to these alternative suppliers, and demonstrate comparability of material produced by such new suppliers. New manufacturers of any product candidate or intermediate would be required to qualify under applicable regulatory requirements. These manufacturers may not be able to manufacture our product candidates at costs, or in sufficient quantities, or in a timely manner necessary to complete development of our product candidates or make commercially successful products. If we are unable to arrange for alternative third-party manufacturing sources, or to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. In addition, should the FDA or comparable regulatory authorities not agree with our product candidate specifications and comparability assessments for these materials, further clinical development of our product candidate could be substantially delayed and we would incur substantial additional expenses.

Reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including reliance on the third party for regulatory compliance and quality assurance, the possibility that the third-party manufacturer does not maintain the financial resources to meet its obligations under the manufacturing agreement, the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control, including a failure to manufacture our product candidates or any products we may eventually commercialize in accordance with our specifications, misappropriation of our proprietary information, including our trade secrets and know-how, and the possibility of termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or damaging to us. In addition, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP, CGTP and similar regulatory jurisdictional standards. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. The FDA or similar foreign regulatory agencies may also implement new standards at any time or change their interpretations and enforcement of existing standards for manufacture, packaging or testing of products. We have limited control over our manufacturers' compliance with these regulations and standards and although we monitor our manufacturers, we depend on them to provide honest and accurate information. Any failure by our third-party manufacturers to comply with cGMP or CGTP or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, including on account of the outbreak of infectious disease, such as the COVID-19 pandemic, could lead

to a delay in, or failure to obtain, regulatory approval of any of our product candidates. In addition, such failure could be the basis for the FDA to issue a warning letter, withdraw approvals for product candidates previously granted to us, or take other regulatory or legal action, including recall or seizure of outside supplies of the product candidate, total or partial suspension of production, suspension of ongoing clinical studies, refusal to approve pending applications or supplemental applications, detention or product, refusal to permit the import or export of products, injunction or imposing civil and criminal penalties.

We are dependent on a limited number of suppliers and, in some instances, a sole supplier, for some of our components and materials used in our product candidates.

We currently depend on a limited number of suppliers and, in some instances, a sole supplier, for some of the components and equipment necessary for the production of consumables, raw materials and starting materials used in the drug product manufacturing process. Specifically, we utilize single sourced suppliers for cell culture media, peptides, cytokines and drug product formulation buffers for the manufacturing of drug product. 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 decides not to continue producing these materials for us. Our use of a sole or a limited number of suppliers of raw materials, components and finished goods exposes us to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. There are, in general, relatively few alternative sources of supply for these components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. For example, the FDA or EMA could require additional supplemental data, manufacturing data and comparability data up to and including clinical trial data if we rely upon a new supplier. Any disruption in supply from any supplier or manufacturing location could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we are required to switch to a replacement supplier, the manufacture and delivery of our product candidates could be interrupted for an extended period, adversely affecting our business. Establishing additional or replacement suppliers may not be accomplished quickly. While we seek to maintain adequate inventory of the components and materials used in our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to conduct our clinical trials and, if our product candidates are approved, to meet the demand of our customers and cause them to cancel orders.

In addition, as part of the FDA's approval of our product candidates, the FDA must review and approve the individual components of our production process, which includes raw materials, the manufacturing processes and facilities of our suppliers. Some of our current suppliers have not undergone this process nor have they had any components included in any product approved by the FDA.

Our reliance on these suppliers subjects us to a number of risks that could harm our reputation, business, and financial condition, including, among other things:

- the interruption of supply resulting from modifications to or discontinuation of a supplier's operations;
- delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier's variation in a component;
- a lack of long-term supply arrangements for key components with our suppliers;
- the inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms;
- difficulty and cost associated with locating and qualifying alternative suppliers for our components in a timely manner;
- production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications;
- a delay in delivery due to our suppliers prioritizing other customer orders over ours;
- damage to our reputation caused by defective components produced by our suppliers;
- increased cost of our warranty program due to product repair or replacement based upon defects in components produced by our suppliers; and
- fluctuation in delivery by our suppliers due to changes in demand from us or their other customers.

If any of these risks materialize, costs could significantly increase and our ability to conduct our clinical trials and, if our product candidates are approved, to meet demand for our products could be impacted. Some of these events could be the basis for FDA or other regulatory authority action, including injunction, recall, seizure, or total or partial suspension of production of our product candidates.

If we and our third-party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our or our third-party manufacturers' use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials with a policy limit that we believe is customary for similarly situated companies and adequate to provide us with insurance coverage for foreseeable risks, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological or hazardous materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions, which could adversely affect our business, financial condition, results of operations and prospects.

If our sole raw material suppliers, clinical or commercial drug product manufacturing facility is damaged or destroyed or production at these facilities is otherwise interrupted, our business would be negatively affected.

In the past, and, should we resume development of our product candidates, the manufacturing of posoleucel and ALVR106 VSTs takes place at an external cGMP CMO, and we primarily rely on a single contract testing laboratory for each drug product release test. We also utilize single sourced suppliers for cell culture media, peptides, cytokines and drug product formulation buffers for the manufacturing of drug product. We plan to qualify back up and redundant raw material suppliers and additional CMOs to increase manufacturing capacity. If any manufacturing facility, raw material or drug product in our manufacturing network, or the equipment in these facilities, is either damaged or destroyed, we may not be able to quickly or inexpensively replace our manufacturing capacity or replace it at all. Additionally, changes to the manufacturing process that occur in the transfer or setup of new manufacturing facilities could require that we conduct bridging studies before being able to proceed with either clinical or commercial manufacturing activities. In the event of a temporary or protracted loss of a facility or its equipment, we may not be able to transfer manufacturing to a third party in the time required to maintain supply. Even if we could transfer manufacturing to a third party, the shift would likely be expensive and time-consuming, particularly since the new facility would need to comply with the necessary regulatory requirements or may require regulatory approval before selling any products manufactured at that facility. Such an event could delay our clinical studies or reduce our commercial product sales.

Currently, we maintain insurance coverage against damage to our property and to cover business interruption and research and development restoration expenses. However, our insurance coverage may not reimburse us, or may not be sufficient to reimburse us, for any expenses or losses we may suffer. We may be unable to meet our requirements for our product candidates if there were a catastrophic event or failure of our current manufacturing facility or processes.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

We do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we have been in the past, and, should we resume development of our product candidates, we expect to remain, dependent on third parties to conduct any future clinical trials of our product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our current product candidates and any future product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial

investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the 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. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive cash compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our current product candidates and any future product candidates.

We depend substantially on intellectual property licensed from third parties, including BCM, 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 the exclusive license agreement with BCM for data and know-how, which we refer to as the BCM License, for our intellectual property, data and know-how. The BCM License imposes, and we expect that future license agreements will impose, various development, diligence, commercialization, and other obligations on us. This license may be terminated upon certain conditions. Any termination of this license could result in the loss of significant rights and could harm our ability to commercialize our product candidates. To the extent BCM fails to meet its obligations under the license, which we are not in control of, we may lose the benefits of the BCM License. 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. In addition, the resolution of any such disputes could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may rely on third parties from whom we license proprietary technology to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We may have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves.

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 such licensed intellectual property, our ability to commercialize products could suffer.

We may not realize the benefits of strategic alliances that we may form in the future or of potential future product acquisitions or licenses.

We may desire to form strategic alliances, create joint ventures or collaborations, enter into licensing arrangements with third parties or acquire products or businesses, in each case that we believe will complement or augment our existing business. For instance, we have entered into the BCM License. These relationships or transactions, or those like them, may require us to incur nonrecurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, reduce the potential profitability of the products that are the subject of the relationship or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic alliances and transactions and the negotiation process is time-consuming and complex and there can be no assurance that we can enter into any of these transactions even if we desire to do so. Moreover, we may not be successful in our efforts to establish a strategic alliance or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates and programs as having the requisite potential to demonstrate a positive risk profile. Any delays in entering into new strategic alliances agreements related to our product candidates could also delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market.

If we license products or acquire businesses, we may not be able to realize the benefit of these transactions if we are unable to successfully integrate them with our existing operations and company culture. We cannot be certain that, following an acquisition or license, we will achieve the financial or strategic results that would justify the transaction.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and manufacturing process, or if the scope of the intellectual property protection is not sufficiently broad, our ability to commercialize our product candidates successfully and to compete effectively may be adversely affected.

We rely upon a combination of patents, trademarks, trade secrets and confidentiality agreements—both that we own or possess or that are owned or possessed by our partners that are in-licensed to us under licenses including the BCM License—to protect the intellectual property related to our technology and product candidates. When we refer to "our" technologies, inventions, patents, patent applications or other intellectual property rights, we are referring to both the rights that we own or possess as well as those that we in-license, many of which are critical to our intellectual property protection and our business. For example, our product candidates and platform technology are protected primarily by patents or patent applications of our partners that we have licensed and as confidential know-how and trade secrets. Additionally, our earlier stage product candidates are not yet protected by any patents or patent applications. If the intellectual property that we rely on is not adequately protected, competitors may be able to use our technologies and erode or negate any competitive advantage we may have.

The patentability of inventions and the validity, enforceability and scope of patents in the biotechnology field is highly uncertain because it involves complex legal, scientific and factual considerations, and it has in recent years been the subject of significant litigation. Moreover, the standards applied by the U.S. Patent and Trademark Office, or USPTO, and non-U.S. patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology patents.

There is no assurance that all potentially relevant prior art relating to our patents and patent applications is known to us or has been found in the instances where searching was done. Further, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Thus, we may be unaware of prior art that could be used to invalidate an issued patent or prevent a

pending patent application from issuing as a patent. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim of one of our patents or patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of such claim. For example, we received an NIH grant related to our posoleucel technology prior to the filing of our patent applications covering our posoleucel technology. If the United States or another jurisdiction decides that the NIH grant is relevant prior art to our patent applications, that could affect our ability to obtain valid and enforceable patent claims protecting our posoleucel program. As a consequence of these and other factors, our patent applications may fail to result in issued patents with claims that cover our product candidates in the United States or in other countries.

Even if patents have issued or do successfully issue from patent applications, and even if these patents cover our product candidates, third parties may challenge the validity, ownership, enforceability or scope thereof, which may result in these patents being narrowed, invalidated, circumvented, or held to be unenforceable. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable.

Even if unchallenged, our patents and patent applications or other intellectual property rights may not adequately protect our intellectual property, provide exclusivity for our product candidates or prevent others from designing around our claims. The possibility exists that others will develop products on an independent basis which have the same or similar effect as our product candidates and which do not infringe our patents or other intellectual property rights, or that others will design around the claims of patents that we have had issued that cover our product candidates. If the breadth or strength of protection provided by our patents and patent applications with respect to our product candidates is threatened, it could jeopardize our ability to commercialize our product candidates and dissuade companies from collaborating with us.

We may also desire to seek a license from a third party who owns intellectual property that may be necessary or useful for providing exclusivity for our product candidates, or for providing the ability to develop and commercialize a product candidate in an unrestricted manner. There is no guarantee that we will be able to obtain a license from such a third party on commercially reasonable terms, or at all.

Obtaining and enforcing biopharmaceutical patents is costly, time consuming and complex, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain patents licensed from third parties. We may have limited control over the manner in which our licensors initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that may be licensed to us. It is possible that the licensors' infringement proceeding or defense activities may be less vigorous than if we conduct them ourselves. For example, under the BCM License, we have comment rights on all prosecution; however, BCM is not obligated to proceed in accordance with our comments. In addition, BCM has the first right to institute an action or proceeding against third party infringing activities, although we have step-in right if BCM fails to bring such an action or proceeding. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

We and our partners have filed a number of patent applications covering our product candidates or methods of using or making those product candidates. We cannot offer any assurances about which, if any, patents will be issued with respect to these pending patent applications, the breadth of any such patents that are ultimately issued or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our partners were the first to file any patent application related to a product candidate. We or our partners may also become involved in proceedings regarding our patents, including patent infringement lawsuits, interference or derivation proceedings, oppositions, reexaminations, and *inter partes* and post-grant review proceedings before the USPTO the European Patent Office and other non-U.S. patent offices.

Even if granted, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent generally occurs 20 years after the earliest U.S. non-provisional application is filed. Although various extensions may be available if certain conditions are met, the life of a patent and the protection it affords is limited. If we encounter delays in our clinical trials or in obtaining regulatory approvals, the period of time during which we could exclusively market any of our product candidates under patent protection, if approved, could be reduced. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be vulnerable to competition from biosimilar products, as we may be unable to prevent competitors from entering the market with a product that is similar or identical to our product candidates.

In the United States, a patent that covers an FDA-approved drug or biologic may be eligible for a term extension designed to restore the period of the patent term that is lost during the premarket regulatory review process conducted by the FDA. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, which permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. In the European Union, our product candidates may be eligible for term extensions based on similar legislation. In either jurisdiction, however, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Even if we are granted such extension, the duration of such extension may be less than our request. If we are unable to obtain a patent term extension, or if the term of any such extension is less than our request, the period during which we can enforce our patent rights for that product will be in effect shortened and our competitors may obtain approval to market competing products sooner. The resulting reduction of years of revenue from applicable products could be substantial.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance under the Bayh-Dole Act. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights". March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. Some of our licensed patents are subject to the provisions of the Bayh-Dole Act. If our partners fail to comply with the regulations of the Bayh-Dole Act, they could lose title to any patents subject to such regulations, which could affect our license rights under the patents and our ability to stop others from using or commercializing similar or identical technology and products, or limit patent protection for our technology and products.

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

Filing, prosecuting, enforcing and defending patents on all of our product candidates in all countries throughout the world would be prohibitively expensive. Our intellectual property rights in certain countries outside the United States may be less extensive than those in the United States. In addition, the laws of certain foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we and our partners may not be able to prevent third parties from practicing our inventions in countries outside the United States, or from selling or importing infringing 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 or where we do not have exclusive rights under the relevant patents to develop their own products and, further, may export otherwise-infringing products to territories where we and our partners have patent protection but where enforcement is not as strong as that in the United States. These infringing products may compete with our product candidates in jurisdictions where we or our partners have no issued patents or where we do not have exclusive rights under the relevant patents, or our patent claims and other intellectual property rights may not be effective or sufficient to prevent them from so 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 and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us and our partners to stop the infringement of our patents or marketing of competing products in violation of our intellectual property rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us or our partners. We or our partners may not prevail in any lawsuits that we or our partners initiate, and even if we or our partners are successful, the damages or other remedies awarded, if any, may not be commercially meaningful.

In some jurisdictions including European Union countries, compulsory licensing laws compel patent owners to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our partners are forced to grant a license to third parties under patents relevant to our business, or if we or our partners are prevented from enforcing patent rights against third parties, our competitive position may be substantially impaired in such jurisdictions.

In Europe, expected by the end of 2023, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court, or UPC. This will be a significant change in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. It is our initial belief that the UPC, while offering a cheaper streamlined process, has potential disadvantages to patent holders, such as making a single European patent vulnerable in all jurisdictions when challenged in a single jurisdiction.

In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have predominately primary place of business or profit-making activities in the U.S. and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

We have in-licensed a significant portion of our intellectual property from our partners, including BCM. If we breach any of our license agreements with these partners, we could lose the ability to continue the development and potential commercialization of one or more of our product candidates.

We hold rights under license agreements with our partners, including the BCM License, that are important to our business. Our discovery and development platform is built, in part, around patent rights in-licensed from our partners. Under our existing license agreements, including the BCM License, we are subject to various obligations, including diligence obligations with respect to development and commercialization activities, payment obligations upon achievement of certain milestones and royalties on product sales. If there is any conflict, dispute, disagreement or issue of nonperformance between us and our counterparties regarding our rights or obligations under these license agreements, including any conflict, dispute or disagreement arising from our failure to satisfy diligence or payment obligations, we may be liable for damages and our counterparties may have a right to terminate the affected license. The termination of any license agreement with one of our partners, including BCM, could materially adversely affect our ability to utilize the intellectual property that is subject to that license agreement in our drug discovery and development efforts, our ability to enter into future collaboration, licensing and/or marketing agreements for one or more affected product candidates and our ability to commercialize the affected product candidates. The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Furthermore, a disagreement under any of these license agreements may harm our relationship with the partner, which could have negative impacts on other aspects of our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. Over the long term, if we are unable to successfully register our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

If we are unable to protect the confidentiality of our trade secrets and other proprietary information, the value of our technology could be materially adversely affected and our business could be harmed.

In addition to seeking the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and other elements of our technology, discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, including by enabling them to develop and commercialize products substantially similar to or competitive with our product candidates, thus eroding our competitive position in the market.

Trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, and outside scientific advisors, contractors and collaborators. These agreements are designed to protect our proprietary information. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, collaborators, or outside scientific advisors might intentionally or inadvertently disclose our trade secrets or confidential, proprietary information to our competitors. In addition, our competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, the laws of certain foreign countries do not protect proprietary rights such as trade secrets to the same extent or in the same manner as the laws of the United States. Misappropriation or unauthorized disclosure of our trade secrets to third parties could impair our competitive advantage in the market and could materially adversely affect our business, results of operations and financial condition.

Risks Related to Patents

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, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

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

Changes in either the patent laws or interpretation of the patent laws in the U.S. or non-U.S. jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor's patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affects patent litigation. These include allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review and, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of

our owned or in-licensed patent applications and the enforcement or defense of our owned or in-licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future.

General Risk Factors

We do not know whether an active, liquid and orderly trading market will develop for our common stock or what the market price of our common stock will be and, as a result, it may be difficult for our stockholders to sell shares of our common stock.

Our IPO closed on August 3, 2020. Prior to our IPO, there was no public market for shares of our common stock. Although we have completed our IPO and shares of our common stock are listed and trading on The Nasdaq Global Select Market, an active trading market for our shares may never develop or be sustained. Our stockholders may not be able to sell shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

The trading price of our common stock may be volatile.

The trading price of our common stock is likely 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 and elsewhere in this quarterly report, these factors include:

- the results of our past, or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including, but not limited to, clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns or adverse events related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- our ability to effectively manage our growth;
- the size and growth of our initial virus target markets;
- our ability to successfully treat additional viral diseases;
- 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 viral immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;
- overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to intellectual property or proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including intellectual property 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 market for 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, financial condition, results of operation and future prospects.

On February 9, 2024, we received a letter from the Listing Qualifications Department, or the Staff, of the Nasdaq Stock Market, or Nasdaq, notifying us that, for the last 30 consecutive business days, our common stock had not maintained a minimum closing bid price of $1.00 per share, or the Minimum Bid Price Requirement, pursuant to Nasdaq Listing Rule 5450(a)(1). The Nasdaq letter does not result in the immediate delisting of our common stock from The Nasdaq Global Select Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), or the Compliance Period Rule, we have been provided an initial period of 180 calendar days, or until August 7, 2024, or the Compliance Date, to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180-day period, the closing bid price for our common stock closes at $1.00 or more per share for a minimum of 10 consecutive business days, as required under the Compliance Period Rule, the Staff will provide written notification to us that we comply with the Minimum Bid Price Requirement and the common stock will continue to be eligible for listing on The Nasdaq Global Select Market.

If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, then, under Nasdaq Listing Rule 5810(c)(3)(A)(i), we may transfer to The Nasdaq Capital Market, provided that we meet the continued listing requirement for the market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, except for the Minimum Bid Price Requirement, and we would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period. Following a transfer to The Nasdaq Capital Market, under Nasdaq Listing Rule 5810(c)(3)(A)(ii), we may be eligible for an additional 180 calendar day compliance period.

If we are not eligible for the additional compliance period or it appears to the Staff that we will not be able to cure the deficiency or if the Staff exercises its discretion to not provide such additional compliance period, the Staff will provide written notice to us that our common stock will be subject to delisting. At that time, we may appeal the Staff's delisting determination to a Nasdaq Hearing Panel, or the Panel. We expect that our stock would remain listed pending the Panel's decision. There can be no assurance that, if we do appeal the Staff's delisting determination to the Panel, such appeal would be successful.

We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Requirement. However, there can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement, transfer to The Nasdaq Capital Market, secure a second period of 180 days to regain compliance, or maintain compliance with any of the other Nasdaq continued listing requirements.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant influence over matters subject to stockholder approval.

Our executive officers, directors, and 5% stockholders beneficially owned approximately 60% of our common stock as of December 31, 2023. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our product candidates on terms that are unfavorable to us.

We may seek additional capital through a variety of means, including through private and public equity offerings and debt financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of existing stockholders will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, including incurring additional debt, making capital expenditures, entering into licensing arrangements or declaring dividends. If we raise additional funds from third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms that are not favorable to us. If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts for our product candidates, grant to others the rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves or take other actions that are adverse to our business.

Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our 2020 Stock Option and Incentive 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, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock.

Pursuant to our 2020 Stock Option and Incentive Plan, or 2020 Plan, our management is authorized to grant stock options to our employees, directors, and consultants.

The number of shares of our common stock reserved for issuance under the 2020 Plan increased on January 1, 2023 and shall be cumulatively increased each January 1 thereafter by 5% of the total number of shares of our common 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 do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an emerging growth company for up to five years following 2020, the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company

until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.235 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th, and (2) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to not "opt out" of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

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

As a public company, we 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, or the Exchange Act, which will require, among other things, that we file with the 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, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from the pricing of our IPO. We intend to take advantage of this new legislation but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

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

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common shares, could make it more difficult for you to sell your common stock at a time and price that you deem appropriate 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.

We have broad discretion over the use of our cash and cash equivalents and may not use them effectively.

Our management has broad discretion to use our cash and cash equivalents to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending our use to fund operations, we may invest our cash and cash equivalents in a manner that does not produce income or that loses 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 board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- 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 antitakeover 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 acquirers 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 stockholders to elect directors of their choosing or cause us to take other corporate actions they 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.

Our amended and restated bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein, or the Delaware Forum Provision. The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the Federal Forum Provision, as our principle office is located in Waltham, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our amended and restated bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court and other state courts have upheld the validity of forum

selection provisions purporting to require claims under the Securities Act be brought in federal court , there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our 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 in accordance with generally accepted accounting principles. In connection with our IPO, we began the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock may depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

Risks Related to Novel Coronavirus (COVID-19) Pandemic

Our business could be adversely affected by the effects of health epidemics, such as the COVID-19 pandemic, in regions where third parties for which we rely, including CROs or CMOs, have significant research, development or manufacturing facilities, concentrations of clinical trial sites or other business operations, causing disruption in supplies and services.

Our business could be adversely affected by health epidemics in regions where third parties for which we rely, as in contract research organizations, or CROs, or contract manufacturing organizations, or CMOs, have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of third-party manufacturers and CROs upon whom we rely. The spread of this pandemic caused significant volatility and uncertainty in U.S. and international markets. Another health epidemic such as the COVID-19 pandemic could result in an economic downturn and may disrupt our business and delay our clinical programs and timelines.

The COVID-19 pandemic, which caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by the COVID-19 pandemic may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the COVID-19 pandemic could materially affect our business and the value of our common stock.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a

whole. However, these effects could have a material impact on our operations, and we will continue to monitor the impacts of the COVID-19 pandemic closely.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

As discussed in this Annual Report on Form 10-K, the changes in our business and operations that will occur in connection with our review of strategic alternatives may impact our cybersecurity program in the future. As such, the following section describes the Company's cyber risk management and strategy, and governance related to cybersecurity risks, for the fiscal year that ended December 31, 2023. For more information regarding the changes to our business and operations and associated risks, please see (i) Item 1 – Business, (ii) Item 1A – Risk Factors, and (iii) Item 7 – Management's Discussion and Analysis of Financial Condition and Results of Operations in this Annual Report on Form 10-K.

Cyber Risk Management and Strategy

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. To help protect against risks from cybersecurity threats to these systems, we have implemented cybersecurity processes in accordance with our risk profile and business that are designed to identify, assess, and manage cybersecurity risks .

We leveraged internal and external resources to support our cyber risk management efforts, including security monitoring tools, periodic penetration tests and vulnerability assessments, and employee cybersecurity awareness training. We have in the past also engaged the services of external information security service providers to help support our information technology environment, assist with security monitoring, and help us draft and implement information security policies.

As part of our cybersecurity risk management process, we take a risk-based approach to the evaluation of third-party vendors based on the criticality and size of the vendor. This process has included a review by our external partners, as appropriate.

We have not identified any cybersecurity incidents or threats that have materially affected us or are reasonably likely to materially affect us, including our business strategy, results of operations or financial condition. As mentioned above, the changes in our business and operations may impact our cybersecurity program in the future. In addition, like other companies in our industry, we and our third-party vendors may, from time to time, experience threats and security incidents relating to our third-party vendors' information systems and infrastructure. For more information, please see Item 1A - Risk Factors.

Governance Related to Cybersecurity Risks

Our Vice President, Head of Information Technology meets periodically with representatives from our external partners to, as applicable, review aspects of the Company's cybersecurity processes or evaluate risks from cybersecurity threats. The individual who currently holds the title of Vice President, Head of Information Technology has approximately 20 years of experience in information security and cybersecurity risk management. Our Vice President, Head of Information Technology reports to the Chief Financial Officer.

We have established a process for management, including our Vice President, Head of Information Technology and Chief Financial Officer, to report to the Audit Committee on potential major cybersecurity risks, their potential impact on us, and the steps we take to manage them. The Audit Committee considers identified cybersecurity risks and the steps that the Company's management has taken to monitor and control such risks in connection with the Audit Committee's discussion of the Company's risk assessment and management guidelines, as appropriate. The Audit Committee has periodically reviewed and discussed the Company's cybersecurity risks, including the Company's information security and risk management programs, controls and procedures, as well as high-level review of the threat landscape facing the Company and the Company's strategy to mitigate cybersecurity risks and potential security incidents.

Our board of directors oversees management of our cybersecurity risks through the Audit Committee. As needed, the chairperson of the Audit Committee provides updates on the Company's cybersecurity risk program to the full board of directors.

Item 2. Properties.

We conduct our primary operations out of leased space in Waltham, MA, which is intended for general office, research and development, laboratory use, and light manufacturing. Our Waltham, Massachusetts property is comprised of a lease with BP Bay Colony, LLC and a sublease of office space with AMAG Pharmaceuticals, Inc. We have rights to the leased space in Waltham through July 30, 2030. We also lease an office space containing a one room suite with workplace capacity for four individuals located in Dublin, Ireland. This lease expires on June 30, 2024. We believe that our current facilities are sufficient to meet our current and near-term needs and that, should it be needed, suitable additional space will be available.

Item 3. Legal Proceedings.

From time to time, we may become subject to arbitration, litigation or claims arising in the ordinary course of business. On January 19, 2024, a purported stockholder of the Company filed a lawsuit, captioned Zerbato v. AlloVir, Inc. et al., No. 1:24-cv-10152 (D. Mass.), in Massachusetts federal court against the Company and two of its officers purportedly on behalf of a putative class of stockholders consisting of persons who purchased or otherwise acquired Company securities between March 22, 2022 and December 21, 2023, inclusive. The complaint purports to assert claims under Section 10(b) and 20(a) of the Securities Act of 1934, as amended, and the related regulations, alleging that the defendants made false and misleading statements and omissions to investors relating to the Company's three Phase 3 studies of posoleucel. The complaint seeks, among other things, damages, prejudgment and post-judgment interest, and attorneys' fees, expert fees and other costs. The Company intends to vigorously defend against the lawsuit.

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.

Market Information

Our common stock began trading on The Nasdaq Global Select Market on July 30, 2020, under the symbol "ALVR." Prior to that time, there was no public market for our common stock.

Holders of Record

As of March 8, 2024, we had approximately 54 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common stock or any other securities. We anticipate that we will retain all available funds and any future earnings, if any, for use in the operation of our business and do not anticipate paying cash dividends in the foreseeable future. In addition, future debt instruments may materially restrict our ability to pay dividends on our common stock. Payment of future cash dividends, if any, will be at the discretion of the board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs, the requirements of then-existing debt instruments and other factors the board of directors deems relevant.

Recent Sales of Unregistered Securities

We deemed the equity grants and exercises of stock options issued under our equity compensation plans prior to the completion of our initial public offering in August 2020 to be exempt from registration in reliance on Rule 701 of the Securities Act as offers and sales of securities under compensatory benefit plans and contracts relating to compensation. Each of the recipients of securities in any transaction exempt from registration either received or had adequate access, through employment, business or other relationships, to information about us.

Use of Proceeds

On August 3, 2020, we closed our initial public offering, in which we issued and sold an aggregate of 18,687,500 shares of common stock, including the additional shares granted to the underwriters, at a public offering price of $17.00 per share. This included the full exercise of the underwriters' over-allotment option to purchase an additional 2,437,500 shares.

All of the shares of common stock sold in our IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (Reg. No. 333-239698 and Reg. No. 333-240181), which was declared effective on July 29, 2020. Following the sale of the shares in connection with the closing of our initial public offering, the offering terminated. Morgan Stanley & Co. LLC, J.P Morgan Securities LLC and SVB Leerink LLC acted as joint book-running managers and Piper Sandler & Co. acted as co-manager of the IPO.

The aggregate net proceeds to use from the public offering were $292.0 million, inclusive of proceeds from the over-allotment exercise, after deducting underwriting discounts and commissions and offering expenses payable by us. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning 10% or more of any class of our equity securities or to any other affiliates.

Information related to use of proceeds from registered securities is incorporated herein by reference to the "Use of Proceeds" section of our final prospectus related to the IPO. There has been no material change in our planned use of the net proceeds from the offering as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on July 30, 2020.

On July 26, 2022, we entered into the Securities Purchase Agreement with certain investors for aggregate net proceeds of $126.4 million after deducting issuance costs of $0.2 million. Pursuant to the terms of the Securities Purchase Agreement, we agreed to issue and sell to the investors in a registered direct offering an aggregate of 27,458,095 shares of our common stock, at a purchase price of $4.61 per share.

On June 21, 2023, we entered into an underwriting agreement with J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC and BoFA Securities, Inc., as the representatives of the several underwriters, or Underwriters, relating to an underwritten public offering of

20,000,000 shares of our common stock at a public offering price of $3.75 per share, resulting in net proceeds of $70.2 million after deducting underwriting discounts, commissions and offering costs.

Issuer Purchases of Equity Securities

None.

Item 6. Reserved.

Not applicable.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations and intentions. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a cell therapy company developing highly innovative allogeneic T cell therapies to treat and prevent devastating viral diseases. Our innovative and proprietary virus-specific T cell, or VST, therapy platform allows us to generate off-the-shelf VSTs designed to restore immunity in patients with T cell deficiencies who are at risk from the life-threatening consequences of viral diseases. There is an urgent medical need for therapies to treat a large number of patients suffering from viral diseases who currently have limited or no treatment options. Our platform includes three innovative, allogeneic, off-the-shelf VST therapy candidates targeting 11 different devastating viruses. Our lead product candidate, posoleucel (previously referred to as Viralym-M or ALVR105), is a multi-VST therapy that targets six viruses: adenovirus, or AdV, BK virus, or BKV, cytomegalovirus, or CMV, Epstein-Barr virus, or EBV, human herpesvirus 6, or HHV-6, and JC virus, or JCV.

In December 2023, we announced the discontinuation of three Phase 3 registrational trials of posoleucel following separate, pre-planned DSMB futility analyses that concluded the studies were unlikely to meet their primary endpoints. Specifically, we discontinued a multicenter, randomized, double-blind, placebo-controlled Phase 3 trial comparing posoleucel to placebo for the prevention of infection or disease due to AdV, BKV, CMV, EBV, HHV-6, or JCV in high-risk adult and pediatric patients after undergoing an allogeneic hematopoietic stem cell transplant. We also discontinued two multicenter, randomized, double-blind, placebo-controlled Phase 3 trials of posoleucel – one for the treatment of virus-associated hemorrhagic cystitis and the second for the treatment of adenovirus infection – both after allogeneic hematopoietic cell transplant.

In December 2023, we also announced that we would review the detailed datasets from those Phase 3 trials and launch a comprehensive review of strategic alternatives focused on maximizing stockholder value, including, but not limited to, a merger, sale, divestiture of assets, licensing, or other strategic transaction. We expect to devote substantial time and resources to exploring strategic alternatives that our board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. We have not set a timetable for completion of this strategic review process, and our board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value, or that we will make any cash distributions to our stockholders. In connection with the evaluation of strategic alternatives and in order maximize capital preservation, we have implemented a plan to reduce our workforce by approximately 95%. This workforce reduction plan was approved in January 2024, and will take place primarily during the first quarter of 2024 and is expected to be substantially completed by April 15, 2024.

Our pipeline includes additional investigational VST therapies that may benefit high-risk individuals. ALVR106 is our second off-the-shelf, multi-VST product candidate targeting devastating respiratory diseases caused by human metapneumovirus, or hMPV, influenza, parainfluenza virus, or PIV and respiratory syncytial virus, or RSV. A Phase 1b/2 POC clinical study of ALVR106 has completed enrollment of patients in Part A of the trial. We have paused development of ALVR106, including discontinuing the trial pending the outcome of our review of strategic alternatives. In the preclinical space, preclinical and IND-enabling studies of ALVR107 to treat and cure HBV were completed in 2022 to support advancement into a POC study. Clinical development of ALVR107 is currently paused pending the outcome of our review of strategic alternatives.

Since inception, we have devoted substantially all of our resources on raising capital, organizing and staffing our company, business planning, conducting discovery and research activities, acquiring or discovering product candidates, establishing and protecting our intellectual property portfolio, developing and progressing posoleucel, ALVR106, ALVR107, and other product candidates and preparing for clinical trials and establishing arrangements with third parties for the manufacture of our product candidates and component materials. We do not have any product candidates approved for sale and have not generated any revenue from product sales.

On August 3, 2020, we completed an initial public offering, or IPO, of our common stock and issued and sold 18,687,500 shares of our common stock at a public offering price of $17.00 per share, resulting in net proceeds of $292.0 million after deducting underwriting discounts and commissions and offering costs. Prior to our IPO, we funded our operations through equity financings and received proceeds of $156.3 million, net of offering costs of $0.6 million, from the sale of our preferred stock.

On July 26, 2022, we entered into a Securities Purchase Agreement, or the Securities Purchase Agreement, with certain investors for the issuance and sale of 27,458,095 shares of our common stock for aggregate net proceeds of $126.4 million.

On June 21, 2023, we entered into an underwriting agreement with J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC and BoFA Securities, Inc., as the representatives of the several underwriters, or Underwriters, relating to an underwritten public offering of 20,000,000 shares of our common stock at a public offering price of $3.75 per share, resulting in net proceeds of $70.2 million after deducting underwriting discounts, commissions and offering costs.

On August 6, 2021, we filed an automatically effective registration statement on Form S-3, or Registration Statement, with the SEC which registered the offering, issuance and sale of an unspecified amount of common stock, preferred stock, debt securities, warrants and/or units of any combination thereof. We simultaneously entered into a sales agreement with SVB Leerink LLC, as sales agent, to provide for the issuance and sale by the Company of up to $100.0 million of common stock from time to time in "at-the-market" offerings under the Registration Statement and related prospectus filed with the Registration Statement, or the ATM Program. On February 10, 2022 we filed a Post-Effective Amendment No. 2 to the Registration Statement and on February 18, 2022 we filed Post-Effective Amendment No. 3 to the Registration Statement. On June 21, 2023, we suspended our use of and terminated the prospectus supplement under the ATM Program. We will not make any sales under the ATM Program unless and until a new prospectus supplement or a new registration statement is filed. Other than the termination of the prospectus supplement, the sales agreement remains in full force and effect. As of December 31, 2023, no sales had been made pursuant to the ATM Program.

We have incurred significant operating losses since inception, including net losses of $190.4 million and $168.7 million for the years ended December 31, 2023 and 2022, respectively. At December 31, 2023, we had an accumulated deficit of $656.2 million.

These losses have resulted primarily from costs incurred in connection with research and development activities and general and administrative costs associated with our operations. We expect losses to decrease in the foreseeable future due to our workforce reduction plan and discontinuation of our clinical trials. We expect to continue to incur costs and expenditures in connection with our ongoing evaluation of strategic alternatives and we will continue to incur costs associated with operating as a public company. There can be no assurance, however, that we will be able to successfully consummate any particular strategic transaction. The process of evaluating strategic transactions has been and may continue to be costly, time-consuming and complex, and we may incur significant costs related to these processes, such as legal, accounting and advisory fees and expenses and other related charges. A considerable portion of these costs will be incurred regardless of whether any particular course of action is implemented or transaction is completed. Any such expenses will decrease the remaining cash available for use in our business. In addition, any strategic business combination or other transactions that we may consummate in the future, could have a variety of negative consequences and we may implement a course of action or consummate a transaction that yields unexpected results that adversely affects our business and decreases the remaining cash available for use in our business or the execution of our strategic plan. There can be no assurances that any particular course of action, business arrangement, transaction, or series of transactions, will be pursued, successfully consummated, lead to increased stockholder value or achieve the anticipated results. Any failure of such potential transaction to achieve the anticipated results could significantly impair our ability to enter into any future strategic transactions and may significantly diminish or delay any future distributions to our stockholders.

Should we resume the development of product candidates, we expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, particularly if and as we:

- initiate and conduct additional preclinical studies and clinical trials for our product candidates;
- continue to discover and develop additional product candidates;
- acquire or in-license other product candidates and technologies;
- maintain, expand, and protect our intellectual property portfolio;
- hire additional clinical and scientific personnel;
- expand our manufacturing capabilities with third parties and establish manufacturing capabilities in-house;
- seek regulatory approvals and pursue commercialization for any product candidates that successfully complete clinical trials; and
- add operational, financial, and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

Should we resume the development of product candidates, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect

to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

At December 31, 2023, we had cash, cash equivalents and short-term investments of $183.9 million. Based on current projections, we believe that our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements through at least twelve months following the issuance of these financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. However, due to the discontinuation of our clinical trials and research activities, as well as our workforce reduction plan, management has concluded that there is a substantial doubt regarding our ability to continue as a going concern for more than twelve months after the date the consolidated financial statements are available to be issued. See "—Liquidity and Capital Resources."

Should we resume the development of product candidates, the development of our product candidates could be disrupted and materially adversely affected in the future by a pandemic, epidemic or outbreak of an infectious disease, such as the COVID-19 pandemic. The spread of COVID-19 impacted the global economy and our operations, including the interruption of our preclinical and clinical trial activities and potential interruption to our supply chain. For example, the COVID-19 pandemic delayed clinical trials. Although the immediate impacts of COVID-19 have receded, if the disruption due to COVID-19 resurges, our planned pivotal clinical trials also could be delayed due to government orders and site policies on account of a pandemic like the COVID-19 pandemic, and some patients may be unwilling or unable to travel to study sites, enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct preclinical studies and clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. Furthermore, COVID-19 could affect our employees or the employees of research sites and service providers on whom we rely, including CROs, as well as those of companies with which we do business, including our suppliers and CMOs, thereby disrupting our business operations.

We cannot presently predict the scope of any potential business shutdowns or disruptions, but if we or any of the third parties on whom we rely or with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and adversely impacted.

Relationship with ElevateBio - Related Party

On September 17, 2018, we entered into a Series A2 Preferred Stock Purchase Agreement, or the Series A2 Agreement, with ElevateBio, and ElevateBio was a purchaser in our registered direct offering in July 2022. ElevateBio, through its diverse platform of technologies to support cell and gene therapy products and expertise, provides drug development and manufacturing services. As a result of ElevateBio's purchase of our Series A2 Preferred Stock, which converted to common stock upon completion of our IPO, and as a result of ElevateBio's participation in the July 2022 registered direct offering, ElevateBio acquired an ownership interest in the Company. The Chief Financial Officer of ElevateBio currently serves in a similar management role with us. In May 2021, Diana M. Brainard M.D., succeeded David Hallal, ElevateBio's Chief Executive Officer, as the Company's Chief Executive Officer. Mr. Hallal currently serves as Executive Chairman of the Company's board of directors. In addition to Mr. Hallal and Mr. Sinha, Morana Jovan-Embiricos, a director of the Company's board of directors, also serves as a director of the board of directors of ElevateBio.

Components of Results of Operations

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with our research and development activities, including our drug discovery efforts and the development of our product candidates. We expense research and development costs as incurred, which include:

- external research and development expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our clinical trials and other scientific development services;
- costs related to manufacturing material for our clinical trials, including fees paid to CMOs;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing clinical trial materials;
- employee-related expenses, including salaries, bonuses, benefits, stock-based compensation and other related costs for those employees involved in research and development efforts;

- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of acquiring and developing clinical trial materials;
- expenses to acquire technologies, such as intellectual property, to be used in research and development;
- upfront and maintenance fees incurred under license, acquisition and other third-party agreements;
- costs related to compliance with regulatory requirements; and
- facilities, depreciation, and other expenses, which include direct and allocated expenses for rent, maintenance of facilities and equipment and software.

Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our discovery studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

We characterize research and development costs incurred prior to the identification of a product candidate as discovery costs. Once a product candidate has been identified, research and development costs incurred are allocated as product candidate costs.

Our direct, external research and development expenses consist primarily of fees paid to outside consultants, CROs, CMOs and research laboratories in connection with our process development, manufacturing and clinical development activities. Our direct external research and development expenses also include fees incurred under license and intellectual property purchase agreements. We track these external research and development costs on a program-by-program basis once we have identified a mature product candidate.

We do not allocate employee costs, costs associated with our discovery efforts, and facilities, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources and third-party consultants primarily to conduct our research and discovery activities as well as for managing our process development, manufacturing and clinical development activities.

Research and development activities have historically been central to our business model. We expect our research and development expenses to continue to decrease significantly given the discontinuation of our clinical trials and research activities and workforce reduction plan. Should we resume development of product candidates, we would expect research and development costs to increase significantly for the foreseeable future as the product candidate development programs progress.

Should we resume development of our product candidates, the duration, costs and timing of development activities including clinical trials would depend on a variety of factors, including:

- the scope, rate of progress and expenses of our ongoing research activities and clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

Should we resume development of our product candidates, any changes in the outcome of any of these variables with respect to the development of our product candidates in clinical development could mean a significant change in the costs and timing associated with the development of these product candidates. We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. For example, if the FDA, the European Medicines Agency, or the EMA, or another regulatory authority were to delay our planned start of clinical trials or require us to conduct clinical trials or other testing beyond those that we currently expect or if we experience significant delays in enrollment in any of our planned clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related costs, including salaries, bonuses, benefits, stock-based compensation and other related costs, as well as expenses for outside professional services, including legal, accounting and audit services and other consulting fees, rent expense and other general administrative expenses.

Impairment Costs

Impairment costs consist primarily of costs incurred from the impairment of long-lived assets as a result of our December 2023 announcement of the discontinuation of our three Phase 3 registrational trials and a comprehensive review of strategic alternatives.

Total Other Income (Loss), Net

Interest income

Interest income consists of interest income on cash, cash equivalents and short-term investments held in financial institutions.

Other income (loss), net

Other income (loss), net consists primarily of investment amortization and accretion of discounts and premiums on short-term investments and foreign exchange gains and losses.

Income tax benefit

Income tax benefit consists of current income tax benefit which is expected to be refundable for the current year.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations (in thousands):

	Years Ended December 31,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 133,070	$ 118,870	$ 14,200
General and administrative	48,261	52,332	(4,071)
Impairment costs	18,570	—	18,570
Total operating expenses	199,901	171,202	28,699
Loss from operations	(199,901)	(171,202)	(28,699)
Total other income (loss), net:			
Interest income	5,734	1,876	3,858
Other income (loss), net	3,623	351	3,272
Loss before income taxes	(190,544)	(168,975)	(21,569)
Income tax benefit	(126)	(265)	139
Net loss	$ (190,418)	$ (168,710)	$ (21,708)

Research and Development Expenses

The following table summarizes our research and development costs for each of the periods presented (in thousands):

	Years Ended December 31,		
	2023	2022	Change
Direct research and development expenses by program:			
posoleucel	$ 79,418	$ 58,629	$ 20,789
ALVR106	1,461	4,313	(2,852)
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	44,252	47,541	(3,289)
Other expenses	7,939	8,387	(448)
Total research and development expenses	$ 133,070	$ 118,870	$ 14,200

Research and development expenses were $133.1 million for the year ended December 31, 2023, compared to $118.9 million for the year ended December 31, 2022. The increase of $14.2 million was primarily due to:

- a $20.8 million increase in costs related to the development of posoleucel, primarily due to an increase in costs related to the outsourcing of manufacturing of $12.2 million and the development of clinical trials of $8.6 million;
- a $2.9 million decrease in costs related to the development of ALVR106, primarily due to a reduction in costs related to the outsourcing of manufacturing of $1.7 million and the development of clinical trials of $1.2 million; and
- a $3.3 million decrease in personnel expenses, including stock-based compensation expense, primarily due to a decrease in consulting costs of $2.3 million and stock-based compensation expense of $0.9 million.

General and Administrative Expenses

General and administrative expenses were $48.3 million for the year ended December 31, 2023, compared to $52.3 million for the year ended December 31, 2022. The decrease of $4.1 million primarily consisted of a decrease in insurance related costs of $1.7 million and a decrease in consulting and personnel expenses, including stock-based compensation, of $1.0 million.

Impairment Costs

Impairment costs were $18.6 million for the year ended December 31, 2023, including $16.6 million related to operating leases, $1.4 million related to implementation costs associated with cloud computing arrangements, and $0.5 million related to property and equipment, due to the December 2023 announcement of the discontinuation of our three Phase 3 registrational trials and a comprehensive review of strategic alternatives.

Total Other Income (Loss), Net

Total “other income (loss), net” was $9.4 million for the year ended December 31, 2023, compared to $2.2 million for the year ended December 31, 2022. The increase of $7.1 million is primarily attributable to an increase of $3.9 million in interest income, an increase of $2.6 million in accretion of discounts on short-term investments, and a decrease of $0.6 million in foreign exchange losses.

Liquidity and Capital Resources

Sources of Liquidity

At December 31, 2023, we have funded our operations primarily through equity financings and have received net cash proceeds of approximately $156.3 million from the sale of our preferred stock, $292.0 million of net proceeds from the sale of common stock in our IPO, $126.4 million of net proceeds from the Securities Purchase Agreement entered into on July 26, 2022 and $70.2 million of net proceeds from the public offering pursuant to the Underwriting Agreement entered into on June 21, 2023.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity over the next five years, other than our manufacturing, licensing and lease obligations described further below.

Funding Requirements

At December 31, 2023, our cash, cash equivalents and short-term investments were $183.9 million. We believe that our existing cash, cash equivalents and short-term investments will enable us to fund our operating expenses and capital expenditure requirements through at least twelve months following the issuance of these financial statements. However, in light of the discontinuation of all of our clinical trials and research activities, as well as our workforce reduction plan, we have concluded that there is a substantial doubt regarding our ability to continue as a going concern for at least twelve months following the issuance of these financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could expend our capital resources sooner than we expect.

We expect our research and development expenses to continue to decrease significantly given the discontinuation of our clinical trials and research activities and workforce reduction plan. We will continue to incur costs associated with operating as a public company, and will also incur costs associated with our review of strategic alternatives.

Should we resume development of product our candidates, however, we expect our expenses to increase in order to advance our product candidates through clinical development, seek regulatory approval and pursue commercialization of any approved product candidates. We expect that our research and development and general and administrative costs will increase in connection with our planned research and development activities. If we receive regulatory approval for our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We may also require additional capital to pursue in-licenses or acquisitions of other product candidates.

We have based these estimates on assumptions that may prove to be imprecise, and we may use our available capital resources sooner than we currently expect. In addition, our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process. Because our resource requirements could materially change depending on the outcome of our ongoing strategic alternative review process, we are unable to estimate the exact amount of our working capital requirements. Should we resume development of our product candidates in the future, our future funding requirements would depend on and could increase significantly as a result of many factors, including:

- the scope, progress, results and costs of researching and developing posoleucel for our initial and potential additional indications, as well as ALVR106 and other product candidates we may develop, including any delays related to a public health epidemic, such as COVID-19,-or other effects on our development programs;
- the timing of, and the costs involved in, obtaining marketing approvals for posoleucel for our initial and potential additional indications, and ALVR106 and other product candidates we may develop;
- if approved, the costs of commercialization activities for posoleucel for any approved indications, or ALVR106 or any other product candidate that receives regulatory approval to the extent such costs are not the responsibility of a collaborator that we may contract with in the future, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of posoleucel for any approved indications or ALVR106 or any other product candidates;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies;
- our headcount growth and associated costs should we expand our research and development, increase our office space, and/or establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the ongoing costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our cost structure, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations and other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common shareholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we resume the development of our product candidates and are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product

development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Cash Flows

The following table summarizes our cash flows for each of the periods presented (in thousands):

	Years Ended December 31,	
	2023	2022
Net cash used in operating activities	$ (124,451)	$ (142,052)
Net cash provided by (used in) investing activities	37,985	(80,478)
Net cash provided by financing activities	70,495	126,961
Net decrease in cash, cash equivalents, and restricted cash	$ (15,971)	$ (95,569)

Operating Activities

Net cash used in operating activities was $124.5 million for the year ended December 31, 2023, reflecting a net loss of $190.4 million, partially offset by non-cash charges of $63.9 million. Non-cash charges primarily consist of stock compensation expense of $40.8 million, impairment costs of $18.6 million and non-cash lease expense of $7.9 million.

Net cash used in operating activities was $142.1 million for the year ended December 31, 2022, reflecting a net loss of $168.7 million, partially offset by non-cash charges of $42.8 million. The non-cash charges primarily consist of stock-based compensation expense of $41.3 million. The change in our net operating assets and liabilities of $(16.1) million was primarily due to a decrease of $12.6 million in accounts payable, accrued expenses and amount due to related party, and an increase of $3.0 million in prepaid expenses and other current assets and prepaid expenses to related party.

The $17.6 million decrease in cash used in operating activities for the year ended December 31, 2023 compared to the year ended December 31, 2022 was primarily due to the change in net operating assets and liabilities due to timing.

Investing Activities

Net cash provided by investing activities was $38.0 million for the year ended December 31, 2023, which was primarily due to investment maturities of $163.8 million, partially offset by purchases of investments of $125.8 million.

Net cash used in investing activities was $80.5 million for the year ended December 31, 2022, which was primarily due to purchases of investments of $228.8 million, partially offset by investment maturities of $148.3 million.

Financing Activities

Net cash provided by financing activities was $70.5 million for the year ended December 31, 2023, which was primarily due to net proceeds from the issuance of common stock in our public offering of $70.2 million..

Net cash provided by financing activities was $127.0 million for the year ended December 31, 2022, which was primarily due to net proceeds from the issuance of common stock in our registered direct offering of $126.4 million..

Contractual Obligations

Operating Leases

Operating lease payments represent our commitments for future minimum lease costs under non-cancelable leases for our corporate headquarters in Waltham, MA and for dedicated manufacturing suites for the manufacture of AlloVir products at a third party contract manufacturing organization, or CMO. The total payments for our operating lease obligations at December 31, 2023 is $31.0 million, of which $11.8 million is due in the next twelve months and the remaining payments are due over the term of the respective leases. For additional details regarding our leases, see Note 5 to our consolidated financial statements.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs and other third-party vendors for clinical trials and testing and manufacturing services, which can contain purchase commitments or other noncancelable obligations. Most contracts do not contain

minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of services provided up to one year after the date of cancellation. The amount and timing of such payments are not known.

We may incur potential contingent payments upon our achievement of clinical, regulatory and commercial milestones, as applicable, or we may be required to make royalty payments under license and grant agreements we have entered into with various entities pursuant to which we have in-licensed certain intellectual property. Due to the uncertainty of the achievement and timing of the events requiring payment under these agreements, the amounts to be paid by us are not fixed or determinable at this time. See "Business—Sponsored Research, Collaboration and License Agreements" as well as Note 8 to our consolidated financial statements for a description of our license agreements.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements appearing elsewhere in this report, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Impairment of Long-Lived Assets

We assess the impairment of long-lived assets whenever events or changes in business circumstances indicate that the carrying amounts of the assets may not be fully recoverable. In the case of right-of-use assets for our leases, we determine whether there has been an impairment by comparing the carrying value of the asset to the anticipated undiscounted net cash flows associated with the asset. If such cash flows are less than the carrying value, we write down the asset to its fair value, which may be measured as anticipated discounted net cash flows associated with the asset.

As discussed in Note 5 to our consolidated financial statements included elsewhere in this report, we review our right-of-use assets for impairment at each reporting date or as facts and circumstances change. As a result of our December 2023 announcement of the discontinuation of our three Phase 3 registrational trials, a comprehensive review of strategic alternatives, and our December 2023 notice of termination of the DMS Agreement for our embedded lease for a dedicated manufacturing suite (see Note 5), we determined that there was a triggering event for impairment of our right-of-use assets. As part of our impairment evaluation of the right-of-use assets, we separately compared the estimated undiscounted cash flows from potential sublease income to the net book value of the right-of-use assets. We estimated sublease income using market participant assumptions, including the length of time to enter into a sublease and expected sublease payments, which we evaluated using sublease negotiations or agreements where applicable, current real estate trends, and market conditions. If such potential sublease income exceeded the net book value of the related assets, we did not record an impairment charge. Otherwise, we recorded an impairment charge by reducing the carrying amount of the operating lease right-of-use assets to their estimated fair value, which was determined by discounting the estimated future cash flows by applying a rate that a market participant would require in assuming the risks associated with those cash flows. Determination of these key assumptions is complex and highly judgmental.

During the year ended December 31, 2023, the Company recorded an impairment loss of $16.6 million to the operating lease right-of-use assets. The fair value of the operating lease right-of-use assets was based on estimated subleasing scenarios, which represent the highest and best use of the right-of-use assets. This fair value assessment utilized market participant assumptions, including the anticipated amount and timing of sublease payments using current real estate trends and market conditions. Given the current office lease market rental conditions, our estimates are subject to significant uncertainty. The ultimate amount of sublease income may be significantly lower or higher than the amounts used to record our impairment charges, and we may record additional impairment charges in future periods as our estimates change if we enter into sublease negotiations or execute a sublease agreement. As of December 31, 2023, the remaining right-of-use asset balance is $2.2 million, which could be subject to future impairment.

Emerging Growth Company Status

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. The JOBS Act provides that, among other things, an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. As an emerging growth company, we have irrevocably elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is

required for non-emerging growth public companies on a case-by-case basis. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We intend to rely on certain of the other exemptions and reduced reporting requirements provided by the JOBS Act. As an emerging growth company, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), and (ii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis).

We will remain an emerging growth company until the earlier to occur of (1) the last day of our fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenues of at least $1.235 billion or (c) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common shares that is held by non-affiliates exceeds $700 million as of the last day of our second quarter, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company" meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue was less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations are disclosed in Note 2 to our consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

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

As a smaller reporting company, we are not required to disclose this item.

Item 8. Financial Statements and Supplementary Data.

Our consolidated financial statements, together with the independent registered public accounting firm report thereon, are presented beginning on page F-1 of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rule 13a-15(e) and Rule 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by a company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and our Chief Financial Officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Internal Control Over Financial Reporting

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, our principal executive officer and our principal financial officer, and effected by our board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of our financial reporting and the preparation of financial statements for external purposes in accordance with U.S. generally accepted accounting principles (U.S. GAAP), and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with authorizations of management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Under the supervision of and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework provided in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in (2013 Framework). Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies".

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(e) and Rule 15d-(e) under the Exchange Act that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving the desired control objectives. Our management recognizes that any control system, no matter how well designed and operated, is based upon certain judgments and assumptions and cannot provide absolute assurance that its objectives will be met. Similarly, an evaluation of controls cannot provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been detected.

Item 9B. Other Information.

During the quarter ended December 31, 2023, no director or officer (as defined in Rule 16a-1(f) of the Exchange Act) of the Company adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of the Stockholders and is included herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of the Stockholders and is included herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of the Stockholders and is included herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of the Stockholders and is included herein by reference.

Item 14. Principal Accounting Fees and Services.

Our independent public accounting firm is Deloitte & Touche LLP, Boston, MA, USA, PCAOB Auditor Firm ID 34.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2024 Annual Meeting of the Stockholders and is included herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Consolidated Financial Statements

The following documents are included this Annual Report on Form 10-K:

Report of Independent Registered Public Accounting Firm
Consolidated Financial Statements
Consolidated Balance Sheets
Consolidated Statements of Operations and Comprehensive Loss
Consolidated Statements of Changes in Stockholders' Equity
Consolidated Statements of Cash Flows
Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

All financial statement schedules have been omitted because they are not applicable, not required, or the information required is shown in the consolidated financial statements or the notes thereto.

(3) Exhibits

The exhibits required by Item 601 of Regulation S-K and Item 15(b) of this Annual Report on Form 10-K are listed in the Exhibit Index below. The exhibits listed in the Exhibit Index are incorporated by reference herein.

Exhibit Index

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No.001-39409) filed on August 3, 2020).
3.2	Certificate of Amendment to Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No.001-39409) filed on May 16, 2023).
3.3	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No.001-39409) filed on August 3, 2020).
4.1	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, effective as of May 8, 2019 (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
4.2	Description of the Registrant's securities registered pursuant to Section 12 of the Securities and Exchange Act of 1934, as amended (incorporated by reference to Exhibit 4.2 of the Registrant's Annual Report on Form 10-K (File No. 001-39409) filed on February 12, 2021).
10.1#	2018 Equity Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.2#	2020 Stock Option and Grant Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
10.3#	2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
10.4#	Senior Executive Cash Bonus Plan (incorporated by reference to Exhibit 10.4 of the Registrant's Annual Report on Form 10-K (File No. 001-39409) filed on February 15, 2023).
10.5#	Form of Indemnification Agreement between the Registrant and each of its directors (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.6#	Form of Indemnification Agreement between the Registrant and each of its executive officers (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).

10.7	Lease Agreement between the Registrant and Regus Management Group, LLC, dated as of January 3, 2019, as amended by the Renewal Agreement, entered into on December 10, 2019 (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.8†	Amended and Restated Exclusive License Agreement, by and between Baylor College of Medicine and the Registrant, dated as of May 11, 2020 (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
10.9†	Sponsored Research Agreement, by and between Baylor College of Medicine and the Registrant, dated as of June 18, 2019, as amended by the Amendment to Sponsored Research Agreement, entered into on April 7, 2020 (incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
10.10	Asset Rental Agreement, by and between ElevateBio Management, Inc. and the Registrant, dated as of May 1, 2019 (incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.11	Sublease Agreement, by and between ElevateBio Management, Inc. and the Registrant, dated as of May 1, 2019 (incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.12#	Consulting Agreement, by and between Juan Vera and the Registrant, dated as of October 1, 2018 (incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.13#	Consulting Agreement, by and between Ann Leen and the Registrant, dated as of October 1, 2018 (incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.14†	Redeemable Preferred Stock Redemption Agreement among the Registrant and certain of its stockholders, effective as of September 17, 2018 (incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
10.15#	Executive Employment Agreement by and between the Registrant and Diana Brainard, effective as of March 17, 2021 (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on March 22, 2021).
10.16#	Transition Agreement by and between the Registrant and David Hallal, dated May 18, 2021 (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-39409) filed on August 6, 2021).
10.17#	Consulting Agreement by and between the Registrant and David Hallal, effective as of July 22, 2021 (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-39409) filed on August 6, 2021).
10.18#	Amended and Restated Executive Employment Agreement, by and between the Registrant and Vikas Sinha, dated as of October 2, 2019 (incorporated by reference to Exhibit 10.15 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
10.19#	Executive Employment Agreement, by and between the Registrant and Agustin Melian, dated as of March 21, 2019 (incorporated by reference to Exhibit 10.16 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
10.20#	Executive Employment Agreement, by and between the Registrant and Ercem Atillasoy, dated as of July 14, 2020 (incorporated by reference to Exhibit 10.17 of the Registrant's Annual Report on Form 10-K (File No. 001-39409) filed on February 12, 2021).
10.21†	Exclusive License Agreement, by and between Baylor College of Medicine and the Registrant, dated as of November 30, 2020 (incorporated by reference to Exhibit 10.18 of the Registrant's Annual Report on Form 10-K (File No. 001-39409) filed on February 12, 2021).
10.22†	Research Collaboration Agreement, by and between Baylor College of Medicine and the Registrant, dated as of November 30, 2020 (incorporated by reference to Exhibit 10.19 of the Registrant's Annual Report on Form 10-K (File No. 001-39409) filed on February 12, 2021).

10.23†	First Amendment to Amended and Restated Exclusive License Agreement by and between Baylor College of Medicine and the Registrant, dated as of November 30, 2020 (incorporated by reference to Exhibit 10.20 of the Registrant's Annual Report on Form 10-K (File No. 001-39409) filed on February 12, 2021).
10.24+	Sublease by and between the Registrant and AMAG Pharmaceuticals, Inc., dated September 8, 2021 (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on September 13, 2021).
10.25+	Lease by and between the Registrant and BP Bay Colony LLC, dated September 8, 2021 (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-39409) filed on September 13, 2021).
10.26	Securities Purchase Agreement, dated as of July 26, 2022, by and between the Registrant and the investors identified therein (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed on July 26, 2022).
21.1	List of Subsidiaries of Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Annual Report on Form 10-K (File No. 001-39409) filed on February 10, 2022).
23.1*	Consent of Deloitte & Touche LLP, independent registered public accounting firm.
24.1*	Power of Attorney (included on signature page).
31.1*	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.
31.2*	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.
32.1*	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.
32.2*	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.
97#*	AlloVir, Inc. Compensation Recovery Policy
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

# Indicates a management contract or any compensatory plan, contract or arrangement.

† Portions of this exhibit (indicated by asterisks) have been omitted in accordance with the rules of the Securities and Exchange Commission.

+ Schedules to the Sublease and Lease have been omitted pursuant to Item 601(b)(2) of Regulation S-K because they contain information that is both (i) not material and (ii) of the type that the registrant treats as private and confidential. The registrant will furnish copies of any such schedules to the Securities and Exchange Commission upon request.

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**.**

ALLOVIR, INC.

Date: March 15, 2024

By: /s/ Diana Brainard

Diana Brainard
Chief Executive Officer and Director
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints Diana Brainard with full power of substitution and resubstitution and full power to act as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file 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 attorney-in-fact and agent full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorney-in-fact and agent or her substitute or substitutes may lawfully do or cause to be done by virtue thereof.

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
/s/ Diana Brainard, MD **Diana Brainard**	Chief Executive Officer and Director *(Principal Executive Officer)*	March 15, 2024
/s/ Vikas Sinha **Vikas Sinha**	President, Chief Financial Officer and Director *(Principal Financial Officer and Principal Accounting Officer)*	March 15, 2024
/s/ David Hallal **David Hallal**	Executive Director	March 15, 2024
/s/ Jeffrey Bornstein **Jeffrey Bornstein**	Director	March 15, 2024
/s/ Malcolm Brenner, MD, PhD **Malcolm Brenner, MD, PhD**	Director	March 15, 2024
/s/ Derek Adams, PhD **Derek Adam, PhD**	Director	March 15, 2024
/s/ Morana Jovan-Embiricos, PhD **Morana Jovan-Embiricos, PhD**	Director	March 15, 2024
/s/ Juan F. Vera, MD **Juan F. Vera, MD**	Director	March 15, 2024
/s/ Shawn Tomasello **Shawn Tomasello**	Director	March 15, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements for the Years Ended December 31, 2023 and 2022:

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the stockholders and the Board of Directors of AlloVir, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of AlloVir, Inc. and subsidiaries (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2023, 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 as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company's recurring losses from operations incurred since inception, the expectation of continuing losses for the foreseeable future, and discontinuation of all clinical trials and research activities, as well as the Company's workforce reduction plan, raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 Public Company Accounting Oversight Board (United States) (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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

/s/ Deloitte & Touche LLP

Boston, Massachusetts
March 15, 2024

We have served as the Company's auditor since 2019.

ALLOVIR, INC.
CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 90,121	$ 106,092
Short-term investments	93,822	127,703
Interest receivable	206	157
Prepaid expenses and other current assets	3,486	7,100
Prepaid expenses to related party	—	2,000
Total current assets	187,635	243,052
Restricted cash	852	852
Other assets	122	612
Property and equipment, net	—	930
Operating lease right-of-use assets	2,187	31,633
Total assets	$ 190,796	$ 277,079
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,761	$ 3,004
Accrued expenses	10,086	13,985
Income tax payable	—	128
Operating lease liability, current	10,781	7,165
Amount due to related party	739	56
Total current liabilities	28,367	24,338
Operating lease liability, long-term	16,648	28,222
Total liabilities	45,015	52,560
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; 0 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.0001 par value: 300,000,000 and 150,000,000 shares authorized at December 31, 2023 and December 31, 2022, respectively; 114,153,538 and 93,268,069 shares issued at December 31, 2023 and December 31, 2022, respectively; and 114,148,991 and 93,093,243 shares outstanding at December 31, 2023 and December 31, 2022, respectively	11	9
Additional paid-in capital	802,025	690,753
Accumulated other comprehensive loss	(62)	(468)
Accumulated deficit	(656,193)	(465,775)
Total stockholders' equity	145,781	224,519
Total liabilities and stockholders' equity	$ 190,796	$ 277,079

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

ALLOVIR, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)	Years Ended December 31, 2023	2022
Operating expenses:		
Research and development	$ 133,070	$ 118,870
General and administrative	48,261	52,332
Impairment costs	18,570	—
Total operating expenses	199,901	171,202
Loss from operations	(199,901)	(171,202)
Total other income (loss), net:		
Interest income	5,734	1,876
Other income (loss), net	3,623	351
Loss before income taxes	(190,544)	(168,975)
Income tax benefit	(126)	(265)
Net loss	$ (190,418)	$ (168,710)
Net loss per share — basic and diluted	$ (1.83)	$ (2.20)
Weighted-average common shares outstanding — basic and diluted	104,057,220	76,654,856
Comprehensive loss:		
Net loss	$ (190,418)	$ (168,710)
Other comprehensive income (loss), net of tax:		
Unrealized gain (loss) on available-for-sale securities	406	(313)
Total other comprehensive income (loss)	406	(313)
Comprehensive loss	$ (190,012)	$ (169,023)

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

ALLOVIR, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

(in thousands, except share amounts)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2021	63,565,886	$ 7	$ 522,479	$ (155)	$ (297,065)	$ 225,266
Stock-based compensation	—	—	41,315	—	—	41,315
Issuance of common stock, upon vesting of restricted stock	1,912,210	—	—	—	—	—
Purchase of common stock under the 2020 Employee Stock Purchase Plan	157,052	—	536	—	—	536
Issuance of common stock in registered direct offering, net of $0.2 million issuance costs	27,458,095	2	126,423	—	—	126,425
Unrealized loss on available-for-sale securities	—	—	—	(313)	—	(313)
Net loss	—	—	—	—	(168,710)	(168,710)
Balance at December 31, 2022	93,093,243	$ 9	$ 690,753	$ (468)	$ (465,775)	$ 224,519
Stock-based compensation	—	—	40,779	—	—	40,779
Issuance of common stock, upon vesting of restricted stock	921,505	—	—	—	—	—
Purchase of common stock under the 2020 Employee Stock Purchase Plan	134,243	—	326	—	—	326
Issuance of common stock in public offering, net of underwriting discounts, commissions and offering costs	20,000,000	2	70,167	—	—	70,169
Unrealized gain on available-for-sale securities	—	—	—	406	—	406
Net loss	—	—	—	—	(190,418)	(190,418)
Balance at December 31, 2023	114,148,991	$ 11	$ 802,025	$ (62)	$ (656,193)	$ 145,781

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

ALLOVIR, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Years Ended December 31, 2023	2022
Cash flows from operating activities		
Net loss	$ (190,418)	$ (168,710)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	398	723
Non-cash lease expense	7,893	1,842
Impairment costs	18,570	
Accretion of short-term investment discounts	(3,698)	(1,076)
Stock-based compensation expense	40,779	41,315
Changes in operating assets and liabilities:		
Interest receivable	(49)	(107)
Prepaid expenses and other current assets and prepaid expenses to related party	5,614	(3,028)
Other assets	(900)	490
Income tax payable	(128)	(879)
Accounts payable, accrued expenses, other liabilities and amount due to related party	(2,512)	(12,622)
Net cash used in operating activities	(124,451)	(142,052)
Cash flows from investing activities		
Purchase of short-term investments	(125,827)	(228,806)
Maturities of short-term investments	163,812	148,328
Net cash provided by (used in) investing activities	37,985	(80,478)
Cash flows from financing activities		
Proceeds from issuance of common stock in public offering, net of underwriting discounts, commissions and offering costs	70,169	—
Proceeds from issuance of common stock in registered direct offering, net of issuance costs	—	126,425
Proceeds from issuance of stock under the 2020 Employee Stock Purchase Plan	326	536
Net cash provided by financing activities	70,495	126,961
Net decrease in cash, cash equivalents, and restricted cash	(15,971)	(95,569)
Cash, cash equivalents, and restricted cash at beginning of period	106,944	202,513
Cash, cash equivalents, and restricted cash at end of period	$ 90,973	$ 106,944
Non-cash investing and financing activities		
Unrealized gain (loss) on available-for-sale securities	$ 406	$ (313)
Right-of-use assets obtained in exchange for operating lease liability	$ —	$ 14,717
Reduction of right-of-use asset due to modification and remeasurement	$ (4,904)	$ (5,506)
Purchase of property and equipment included in accounts payable and accrued expenses	$ —	$ 104
Supplemental disclosure of cash flows		
Income taxes paid, net of refunds	$ 220	$ 613

	Years Ended December 31, 2023	2022
Cash and cash equivalents	$ 90,121	$ 106,092
Restricted cash	852	852
Total cash, cash equivalents, and restricted cash	$ 90,973	$ 106,944

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

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business

AlloVir, Inc. ("AlloVir" or "the Company", formerly known as ViraCyte, Inc.) is a cell therapy company developing highly innovative allogeneic T cell therapies to treat and prevent devastating viral diseases. The Company's innovative and proprietary virus-specific T cell, or VST, therapy platform allows AlloVir to generate off-the-shelf VSTs designed to restore immunity in patients with T cell deficiencies who are at risk from the life-threatening consequences of viral diseases. There is an urgent medical need for therapies to treat a large number of patients suffering from viral diseases who currently have limited or no treatment options. The Company's platform includes three innovative, allogeneic, off-the-shelf VST therapy candidates targeting 11 different devastating viruses. The Company's lead product candidate, posoleucel (previously referred to as Viralym-M or ALVR105), is a multi-VST therapy that targets six viruses: adenovirus, or AdV, BK virus, or BKV, cytomegalovirus, or CMV, Epstein-Barr virus, or EBV, human herpesvirus 6, or HHV-6 and JC virus, or JCV.

In December 2023, the Company announced the discontinuation of three Phase 3 registrational trials of posoleucel following separate, pre-planned Data Safety Monitoring Board, or DSMB, futility analyses that concluded the studies were unlikely to meet their primary endpoints. Specifically, the Company discontinued a multicenter, randomized, double-blind, placebo-controlled Phase 3 trial comparing posoleucel to placebo for the prevention of infection or disease due to AdV, BKV, CMV, EBV, HHV-6, or JCV in high-risk adult and pediatric patients after undergoing an allogeneic hematopoietic stem cell transplant. The Company also discontinued two multicenter, randomized, double-blind, placebo-controlled Phase 3 trials of posoleucel – one for the treatment of virus-associated hemorrhagic cystitis and the second for the treatment of adenovirus infection – both after allogeneic hematopoietic cell transplant.

In December 2023, the Company also announced that it would review the detailed datasets from those Phase 3 trials and launch a comprehensive review of strategic alternatives focused on maximizing stockholder value, including, but not limited to, a merger, sale, divestiture of assets, licensing, or other strategic transaction. The Company expects to devote substantial time and resources to exploring strategic alternatives that the board of directors believes will maximize stockholder value. Despite devoting significant efforts to identify and evaluate potential strategic alternatives, there can be no assurance that this strategic review process will result in us pursuing any transaction or that any transaction, if pursued, will be completed on attractive terms or at all. The Company has not set a timetable for completion of this strategic review process, and the board of directors has not approved a definitive course of action. Additionally, there can be no assurances that any particular course of action, business arrangement or transaction, or series of transactions, will be pursued, successfully consummated or lead to increased stockholder value, or that the Company will make any cash distributions to our stockholders. In connection with the evaluation of strategic alternatives and in order maximize capital preservation, the Company has implemented a plan to reduce our workforce by approximately 95%. This workforce reduction plan was approved in January 2024, and will take place primarily during the first quarter of 2024 and is expected to be substantially completed by April 15, 2024.

The Company's pipeline includes additional investigational VST therapies that may benefit high-risk individuals. ALVR106 is the Company's second off-the-shelf, multi-VST product candidate targeting devastating respiratory diseases caused by human metapneumovirus, or hMPV, influenza, parainfluenza virus, or PIV and respiratory syncytial virus, or RSV. A Phase 1b/2 POC clinical study of ALVR106 has completed enrollment of patients in Part A of the trial. The Company has paused development of ALVR106, including discontinuing the trial pending the outcome of the Company's review of strategic alternatives. In the preclinical space, preclinical and IND-enabling studies of ALVR107 to treat and cure HBV were completed in 2022 to support advancement into a POC study. Clinical development of ALVR107 has been paused pending the outcome of the Company's review of strategic alternatives.

Going Concern

In accordance with Accounting Standards Update ("ASU") 2014-15, *Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the consolidated financial statements are issued.

Since its inception and until recently, the Company devoted substantially all of its resources to recruiting personnel, developing its technology platform and advancing its pipeline of product candidates through discovery, preclinical and clinical trials, acquiring and manufacturing clinical trial materials and maintaining and building its intellectual property portfolio. The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, success of clinical trials, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Should the Company resume development of its product candidates, the product candidates will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization.

Through December 31, 2023, the Company has funded its operations primarily with proceeds received from the sale of common stock, research grants, and from the sale of preferred stock. The Company has incurred recurring losses since its inception, including

net losses attributable to common stockholders of $190.4 million for the year ended December 31, 2023 and $168.7 million for the year ended December 31, 2022. In addition, at December 31, 2023, the Company had an accumulated deficit of $656.2 million. The Company expects to continue to generate operating losses for the foreseeable future.

The Company has incurred and expects to continue to incur costs and expenditures in connection with the process of evaluating strategic alternatives. There can be no assurance, however, that the Company will be able to successfully consummate any particular strategic transaction. The process of evaluating strategic options has been and may continue to be costly, time-consuming and complex and the Company may incur significant costs related to this continued evaluation, such as legal, accounting and advisory fees and expenses and other related charges.

Based on current projections, the Company believes that its $183.9 million of cash, cash equivalents and short-term investments held at December 31, 2023 will be sufficient to fund planned operations for at least twelve months from the date that these consolidated financial statements are available to be issued. However, due to the consideration of certain qualitative factors, including the discontinuation of all clinical trials and research activities, as well as the Company's workforce reduction plan, management has concluded there is substantial doubt regarding the Company's ability to continue as a going concern for more than twelve months from the date that the consolidated financial statements are available to be issued. These consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Should the Company resume the development of product candidates, it would need to obtain substantial additional funding in connection with continuing operations, particularly as the Company resumes its preclinical activities and clinical trials for its product candidates. There can be no assurance that the Company will be able to obtain sufficient capital to cover its costs on acceptable terms, if at all.

ElevateBio, LLC - Related Party

On September 17, 2018, the Company executed a Series A2 Preferred Stock Purchase Agreement ("Series A2 Agreement"), with ElevateBio, LLC ("ElevateBio") and ElevateBio was a purchaser in our registered direct offering in July 2022. ElevateBio, through its diverse platform of technologies to support cell and gene therapy products and expertise, provides drug development and manufacturing services. As a result of ElevateBio’s purchase of our Series A2 Preferred Stock, which converted to common stock upon completion of our IPO, and as a result of ElevateBio’s participation in the July 2022 registered direct offering, ElevateBio acquired an ownership interest in the Company. The Chief Financial Officer of ElevateBio currently serves in a similar management role with AlloVir. In May 2021, Diana M. Brainard, M.D. succeeded David Hallal, ElevateBio’s Chief Executive Officer, as the Company’s Chief Executive Officer. Mr. Hallal currently serves as Executive Chairman of the Company’s board of directors. In addition to Mr. Hallal and Mr. Sinha, Morana Jovan-Embiricos, a director of the Company’s board of directors, also serves as a director of the board of directors of ElevateBio.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (“U.S. GAAP”). The consolidated financial statements include the Company’s accounts and those of its wholly-owned subsidiaries. All intercompany accounts, transactions and balances have been eliminated in consolidation.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company has one operating segment. The Company’s singular focus is the research, development and commercialization of off-the-shelf VST therapies to prevent and treat severe viral-associated diseases. The Company’s chief operating decision maker, its Chief Executive Officer, manages the Company’s operations on a consolidated basis for the purpose of allocating resources. All of the Company’s long-lived assets are held in the United States.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are short-term, highly liquid investments with original maturities of three months or less at the date of purchase. Investments qualifying as cash equivalents primarily consist of money market funds, corporate bonds and commercial paper.

Short-Term Investments

Short-term investments consist of U.S. treasury securities and corporate bonds classified as available-for-sale that have maturities of less than one year. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income (loss) until realized. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization or accretion is included in "other income (loss), net". Realized gains and losses are determined using the specific identification method and are included in "other income (loss), net".

Restricted Cash

Cash accounts with any type of restriction are classified as restricted cash. The Company has restricted cash deposits with a bank, which serve as collateral for a letter of credit issued to the landlord of the Company's leased Waltham facility for a security deposit. The Company classified this amount as non-current restricted cash in the accompanying consolidated balance sheet at December 31, 2023 and 2022.

Property and Equipment, Net

The Company records property and equipment at cost and recognizes depreciation using the straight-line method over the estimated useful lives of the respective assets, as follows:

Asset category	Estimated useful life
Computer equipment	3 years
Laboratory equipment	5 years

The Company periodically evaluates whether events and circumstances have occurred that may warrant revision of the estimated useful life of property and equipment. Expenditures for repairs and maintenance of assets are expensed as incurred. Upon retirement or sale, the cost of assets disposed and the corresponding accumulated depreciation are removed from the related accounts and any resulting gain or loss is reflected in the results of operations. Construction in progress is not depreciated until it is placed in service. Property and equipment to be disposed of are carried at fair value less costs to sell.

Impairment of Long-Lived Assets

The Company accounts for long-lived assets in accordance with ASC Topic 360, *Property, Plant, and Equipment* ("ASC 360"). ASC 360 requires companies to: (i) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and (ii) measure an impairment loss as the difference between the carrying amount and the fair value of the asset.

The Company tests long-lived assets to be held and used, including right-of-use assets and property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of assets or asset groups may not be fully recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their fair values. See Note 5 and Note 6 for impairment costs recognized during the years ended December 31, 2023 and 2022.

Fair Value Measurements

ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that

market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or 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 a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2 – Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3 – Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company's financial instruments include cash equivalents, short-term investments, prepaid expenses and other current assets, prepaid expenses to related party, accounts payable, amount due to related party and accrued expenses. Certain of the Company's financial assets, including cash equivalents and short-term investments, have been initially valued at the transaction price, and subsequently revalued at the end of each reporting period, utilizing third-party pricing services or other observable market data. The pricing services utilize industry standard valuation models and observable market inputs to determine value.

Other financial instruments, including prepaid expenses and other current assets, prepaid expenses to related party, accounts payable, amount due to related party and accrued expenses, are carried at cost, which approximate fair value due to the short duration and term to maturity.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are presented in the consolidated balance sheets as a direct reduction from the carrying amount of the respective equity instrument issued. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. At December 31, 2023 and 2022, the Company had no deferred offering costs.

Cloud Computing Arrangements

The Company capitalizes certain implementation costs for internal-use software incurred in a cloud computing agreement that is a service contract. Eligible costs associated with cloud computing arrangements, such as the implementation costs incurred to develop or obtain software business applications used in the normal course of business, are capitalized in accordance with ASC 350. Capitalization ceases at the point the software is substantially complete and ready for its intended use, and after all substantial testing is completed. Amortization is recorded on a straight-line basis over the expected useful life of three years of the internal-use software cost in the same line item in the statement of operations and comprehensive loss as the expense for fees for the associated cloud computing arrangement. Amortization expense associated with the Company's cloud computing arrangements has been recognized in the amount of $0.5 million during the years ended December 31, 2023 and 2022. As a result of the December 2023 announcement of the discontinuation of the Company's three Phase 3 registrational trials and a comprehensive review of strategic alternatives, an impairment loss of $1.4 million was recognized during the year ended December 31, 2023 for implementation costs associated with cloud computing arrangements that are no longer probable of being implemented.

Other Income (Loss), Net

The Company records interest expense, investment amortization and accretion of discounts and premiums on short-term investments and foreign exchange gains and losses in "other income (loss), net" when incurred.

Research and Development Costs

Research and development costs are charged to expense as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including personnel-related costs, stock-based compensation, facilities, research-related overhead, clinical trial costs, contracted services, research-related manufacturing, license fees and other external costs. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the services have been performed or when the goods have been received.

Accrued Research and Development Expenses

The Company has entered into various research and development contracts. The payments under these contracts are recorded as research and development expenses as incurred. The Company records accrued liabilities for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Judgements and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

Stock-Based Compensation Expense

The Company grants restricted stock and stock options to employees, consultants and directors. The Company recognizes stock-based compensation cost for awards with performance conditions if and when it concludes that it is probable that the performance conditions will be achieved. For awards with only a service condition, the Company expenses stock-based compensation on a straight-line basis over the requisite employee service period or for grants issued with performance conditions, on a graded-vesting basis over the requisite employee service period. Awards for employees and non-employees are accounted for similarly. The Company records stock-based compensation expense associated with grants of restricted stock and stock options in the consolidated statements of operations and comprehensive loss based on their estimated fair value at the date of the grant. The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the grantee's payroll costs are classified or in which the grantee's service payments are classified. Forfeitures are accounted for as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. The fair value of the Company's common stock is determined based on the quoted market price of common stock. The Company also lacks company-specific historical and implied volatility information for its stock. The Company estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method. The "simplified" method estimates the expected term of stock options as the mid-point between the weighted average time to vesting and the contractual maturity. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. There is no expected dividend yield since the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Net Loss per Share

Basic and diluted net loss per share is determined by dividing net loss by the weighted-average common stock outstanding during the period. Since we have incurred operating losses for all periods presented, outstanding stock options and unvested restricted common stock have been excluded from the calculation because their effects would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

Income Taxes

The Company accounts for income taxes under the asset and liability method in accordance with ASC 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and

liabilities are measured using enacted rates in effect for the year in which these temporary differences are expected to be recovered or settled. Valuation allowances are provided if based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Management believes that it is more likely than not that all deferred tax assets will not be realized.

The Company recognizes liabilities for potential tax payments to various tax authorities related to uncertain tax positions. The liabilities are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filing is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Potential interest and penalties associated with such uncertain tax positions, if any, are recorded as components of income tax expense.

The Company assesses its income tax positions and records tax benefits for all years subject to examination based upon management's evaluation of the facts, circumstances and information available as of the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50 percent likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the consolidated financial statements.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that subject the Company to credit risk consist primarily of cash, cash equivalents, restricted cash and short-term investments. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and have not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Such deposits have and will continue to exceed federally insured limits. The Company has not experienced any losses on its cash deposits.

At December 31, 2023 and 2022, the Company had no off-balance sheet risk.

Foreign Exchange

The functional currency for all subsidiaries is the U.S. Dollar ("USD"). Transactions in foreign currencies are remeasured into the functional currency of the relevant subsidiaries at the exchange rate in effect at the date of the transaction. Any monetary assets and liabilities arising from these transactions are translated into the functional currency at exchange rates in effect at the balance sheet date or on settlement. Resulting gains and losses are recorded in "other income (loss), net" within the consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. Comprehensive loss includes net loss and certain changes in stockholder's deficit that are excluded from net loss. The Company's comprehensive loss includes unrealized gains (losses) on available-for-sale securities during the year ended December 31, 2023 and 2022.

Leases

In accordance with ASC Topic 842, *Lease Accounting*, at the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. Leases with a term greater than one year are recognized on the consolidated balance sheet as a right-of-use ("ROU") asset and current and non-current lease liabilities, as applicable. The Company has made an accounting policy election, known as the short-term lease recognition exemption, which allows the Company to not recognize ROU assets and lease liabilities that arise from short-term leases (12 months or less) for any class of underlying asset. Options to renew or options to cancel a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew or will not cancel, respectively.

Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected remaining lease term. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Certain adjustments to the ROU asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental

borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

The Company has elected to account for the lease and non-lease components together for all existing classes of underlying assets.

Subsequent Events

The Company evaluates events occurring after the date of our accompanying consolidated balance sheets for potential recognition or disclosure in our consolidated financial statements. The Company did not identify any material subsequent events requiring adjustment to our accompanying consolidated financial statements (recognized subsequent events). Those items requiring disclosure (unrecognized subsequent events) in the consolidated financial statements have been disclosed accordingly. Refer to Note 16 for further details.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB"), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's consolidated financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with certain new or revised accounting standards pursuant to Section 107(b) of the JOBS Act.

Recently Adopted Accounting Pronouncements

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses* (Topic 326): *Measurement of Credit Losses on Financial Instruments*, or ASU 2016-13, which requires the measurement and recognition of expected credit losses for financial assets held at amortized cost. ASU 2016-13 replaces the existing incurred loss impairment model with an expected loss model. It also eliminates the concept of other-than-temporary impairment and requires credit losses related to available-for-sale debt securities to be recorded through an allowance for credit losses rather than as a reduction in the amortized cost basis of the securities. These changes may result in earlier recognition of credit losses. The Company adopted ASU 2016-13 on January 1, 2023. The adoption of ASU 2016-13 did not have a material impact on the Company's consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements Not Yet Adopted

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting* (Topic 280): *Improvements to Reportable Segment Disclosures*, which requires disclosure of incremental segment information on an interim and annual basis. This ASU is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal periods beginning after December 15, 2024, and requires retrospective application to all prior periods presented in the financial statements. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): *Improvements to Income Tax Disclosures*, which requires public entities, on an annual basis, to provide disclosure of specific categories in the rate reconciliation, as well as disclosure of income taxes paid disaggregated by jurisdiction. This ASU is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. The adoption of this standard is not expected to have a material impact on the Company's consolidated financial statements and related disclosures.

3. Short-Term Investments

The following tables summarize the amortized cost and estimated fair value of the Company's U.S. government treasury securities and marketable securities, which are considered to be available-for-sale investments and are included in short-term investments on the consolidated balance sheets:

	December 31, 2023			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government treasury securities	$ 93,749	$ 73	$ —	$ 93,822
Totals	$ 93,749	$ 73	$ —	$ 93,822

	December 31, 2022			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government treasury securities	$ 99,288	$ 1	$ (253)	$ 99,036
Marketable securities:				
Corporate and agency bonds	28,748	3	(84)	28,667
Totals	$ 128,036	$ 4	$ (337)	$ 127,703

Certain short-term debt securities with original maturities of less than three months are included in cash and cash equivalents on the consolidated balance sheets and are not included in the tables above. The Company holds debt securities of companies with high credit quality and has determined that there was no material change in the credit risk of any of its debt securities. At December 31, 2023 and 2022, all investments had contractual maturities within one year.

4. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis:

	December 31, 2023			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$ 23,854	$ —	$ —	$ 23,854
Totals	$ 23,854	$ —	$ —	$ 23,854
Short-term investments:				
U.S. government treasury securities	$ 93,822	$ —	$ —	$ 93,822
Totals	$ 93,822	$ —	$ —	$ 93,822

	December 31, 2022			
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	$ 32,641	$ —	$ —	$ 32,641
Totals	$ 32,641	$ —	$ —	$ 32,641
Short-term investments:				
U.S. government treasury securities	$ 99,036	$ —	$ —	$ 99,036
Marketable securities:				
Corporate and agency bonds	—	28,667	—	28,667
Totals	$ 99,036	$ 28,667	$ —	$ 127,703

During the years ended December 31, 2023 and 2022, there were no transfers between levels. The Company classifies its money market fund and U.S. government treasury securities as Level 1 assets under the fair value hierarchy, as these assets have been valued using quoted market prices in active markets without any valuation adjustment. The Company classifies its marketable securities as Level 2 assets under the fair value hierarchy, as these assets have pricing inputs that are other than quoted prices in active markets, which are either directly or indirectly observable as of the reporting date, and fair value is determined using models or other valuation methodologies.

The carrying amounts of prepaid expenses and other current assets, prepaid expenses to related party, accounts payable, amount due to related party and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities.

5. Leases

Operating leases

Development and Manufacturing Services Agreement ("DMS Agreement") with Third-Party Supplier

In October 2022, the Company entered into a Statement of Work ("SOW") under the DMS Agreement (the "2022 SOW under the DMS Agreement") with a third-party supplier. The 2022 SOW under the DMS Agreement contained an embedded lease for a dedicated manufacturing suite for the manufacture of AlloVir's products at the facility because the Company directs how and for what purpose the suite is used and obtains substantially all of the economic benefit of the suite. At inception of the lease, it was determined that, in exchange for this dedicated manufacturing suite, AlloVir will pay the supplier a monthly fixed suite utilization fee, fixed batch payments and other related fixed costs, totaling $16.3 million over the 2.25 year lease term ending in December 2024. As part of the arrangement, there were also variable costs for materials, non-fixed batch payments, testing, storage, knowledge and tech transfer and other common area maintenance fees that were not included in the measurement of the lease liability. The lease of the facility was determined to be classified as an operating lease and commenced in October 2022, the point at which the suite was substantially complete and available for use by the Company. Accordingly, at inception, the Company recorded a right-of-use asset and lease liability of $14.7 million.

In December 2023, the Company issued a notice of termination of the DMS Agreement effective June 2024, or 190 days from the third-party supplier's receipt of the notice. Management concluded that the notice of termination constituted a lease reassessment under ASC 842 as the Company was granted the option of such termination at the onset of the DMS Agreement and it was previously determined to be reasonably certain of not being exercised. As a result, the remaining lease term was shortened and the Company recorded a $4.9 million reduction to the right-of-use asset and lease liability in December 2023. In February 2024, the Company entered into a new SOW that terminated the 2022 SOW under the DMS Agreement (see Note 16).

Waltham Leases

In September 2021, the Company entered into a lease agreement with BP Bay Colony LLC and a sublease with AMAG Pharmaceuticals Inc. for the lease of property in Waltham, Massachusetts (collectively, the "Waltham leases"). The space identified under the Waltham leases is intended for general office space, research and development, laboratory use, and light manufacturing. The Waltham leases are classified as operating leases and commenced in September 2021. At the inception date, the Company recorded a ROU asset and lease liability of $6.0 million for the lease and a ROU asset and lease liability of $17.3 million for the sublease based on a July 30, 2030 end date for the Waltham leases. As part of the arrangement, there were also variable costs for common area maintenance fees that were not included in the measurement of the lease liability. The agreement also provided a $3.1 million tenant improvement allowance. The Company utilized $0.9 million of the tenant improvement allowance. The Company has the option to renew the leased space for an additional one time period of five years with written notice from the Company. As of December 31, 2023, the Company has no reasonable certainty that this option to extend will be exercised.

Impairment of Lease Right-of-Use Assets

As a result of the December 2023 announcement of the discontinuation of the Company's three Phase 3 registrational trials, a comprehensive review of strategic alternatives, and the December 2023 notice of termination of the DMS Agreement, the Company determined that there was a triggering event for impairment. The Company determined that the operating lease right-of-use assets were not recoverable as the carrying value exceeded the anticipated future cash flows on an undiscounted basis. To measure the impairment, the Company determined the fair value of the operating lease right-of-use assets based on estimated subleasing scenarios, which represent the highest and best use of the right-of-use assets. This fair value assessment utilized market participant assumptions, including the anticipated amount and timing of potential sublease payments using current real estate trends and market conditions. As a result, an impairment charge was calculated by reducing the carrying amount of the operating lease right-of-use assets to their estimated fair value, which was determined by discounting the estimated future cash flows by applying a rate that a market participant would require in assuming the risks associated with those cash flows. During the year ended December 31, 2023, the Company recorded an impairment loss of $16.6 million to the operating lease right-of-use assets. As of December 31, 2023, the remaining right-of-use asset balance is $2.2 million, which relates to the Waltham leases.

Maturities of operating lease liabilities at December 31, 2023 are as follows (in thousands):

2024	11,842
2025	3,219
2026	3,298
2027	3,376
2028	3,455
Thereafter	5,824
Total lease payments	31,014
Less: interest	3,585
Total lease liability	$ 27,429
Lease liability – current	$ 10,781
Lease liability – long-term	$ 16,648

Total lease costs were $9.7 million and $6.6 million for the years ended December 31, 2023 and 2022, respectively. Cash paid for operating leases was $4.8 million and $4.8 million for the year ended December 31, 2023 and 2022, respectively. The Company's total variable lease costs, such as materials, non-fixed batch payments, testing, storage, knowledge and tech transfer, and other common area maintenance fees, related to the operating leases was $0.9 million and $3.7 million for the years ended December 31, 2023 and 2022, respectively. The weighted average remaining lease term is 4.70 years and 6.93 years at December 31, 2023 and 2022, respectively. The weighted average discount rate is 5.95% and 6.23% at December 31, 2023 and 2022, respectively.

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
(in thousands)	2023	2022
Laboratory equipment	$ 1,483	$ 1,395
Computer equipment	435	435
Construction-in-progress	—	104
Total property and equipment	1,918	1,934
Less: accumulated depreciation and impairment	(1,918)	(1,004)
Property and equipment, net	$ —	$ 930

Depreciation expense was $0.4 million and $0.7 million for the years ended December 31, 2023 and 2022, respectively. As a result of the December 2023 announcement of the discontinuation of the Company's three Phase 3 registrational trials and a comprehensive review of strategic alternatives, an impairment loss of $0.5 million was recognized on property and equipment during the year ended December 31, 2023.

7. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
(in thousands)	2023	2022
Employee compensation and benefits	$ 3,809	$ 6,416
Professional fees	435	559
Research and development	2,442	5,678
Process development and manufacturing costs	2,367	504
Other	1,033	828
Total accrued expenses	$ 10,086	$ 13,985

8. Sponsored Research, Collaboration and License Agreements

Amended and Restated Exclusive License Agreement with BCM

In June 2017, the Company signed a License Agreement (the "License Agreement") with BCM, whereby the Company acquired a royalty-bearing, worldwide, exclusive license to BCM's rights in Subject Technology and related patent rights in the field of viral infection. In May 2020, the Company amended and restated the License Agreement (the "A&R License Agreement"), pursuant to which the Company obtained (a) an exclusive worldwide license, with the right to sublicense, under certain patent rights and other intellectual property rights of BCM, to make, have made, use, market, sell, offer to sell, lease, import and export products in a particular field, except that such license is non-exclusive within a particular subfield, and in addition with respect to certain patent rights such license is limited to two particular subfields, and (b) an exclusive, worldwide sublicense, with the right to further sublicense, under all patent rights and other intellectual property rights that are exclusively licensed to BCM by a certain third party licensor, to make, have made, use, market, sell, offer to sell, lease, import and export products in the same field. The Company's rights are subject to the rights of the U.S. government and certain rights retained by BCM.

Unless earlier terminated, the A&R License Agreement will expire on a country-by-country basis with respect to a product upon the later of (a) the expiration of the last to expire valid claim of a patent or patent application covering such product in such country or (b) 10 years after the first commercial sale of such product in such country. The Company may terminate the A&R License Agreement in its entirety at any time for convenience upon a certain number of days' written notice. BCM may terminate the A&R License Agreement in its entirety for the Company's uncured material default.

BCM maintains control of all filing, prosecution and maintenance of its patent rights licensed by the Company, and the Company is responsible for all related costs and expenses during the term of the agreement. The Company also reimbursed BCM for costs and expenses (including reasonable legal fees and expenses) incurred prior to the effective date of the agreement with respect to the filing, prosecution and maintenance of the patent rights licensed by the Company. If BCM licenses the patent rights licensed by the Company to third parties for additional fields of use, the Company's responsibility for patent related costs and expenses will be reduced on a pro-rata basis.

Under the A&R License Agreement, the Company must use commercially reasonable efforts to develop and commercialize one or more products in certain countries. As partial consideration for the rights conveyed by BCM under the original agreement executed in June 2017, the Company paid BCM a non-refundable license fee of $250,000. During the term of the A&R License Agreement, the Company is obligated to pay BCM a non-refundable annual license maintenance fee, but beginning with the fifth year after the original agreement date, license maintenance fees are fully creditable against royalty revenue due in the applicable year. The Company is required to pay certain milestone payments upon the achievement of specified clinical, regulatory, and sales milestones. In the event that the Company is able to successfully develop, launch and commercialize a product under the A&R License Agreement, total milestone payments could exceed $40.0 million. BCM is also eligible to receive tiered royalties at percentage rates ranging from less than 1% to the low single-digits, on net sales of any products that are commercialized by the Company or its sublicensees that incorporate, utilize or are made with the use of, the intellectual property licensed by the Company. To the extent the Company sublicenses its license rights under the A&R License Agreement, BCM would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits.

In November 2020, the Company also entered into the First Amendment (the "License Amendment") to the A&R License Agreement. Under the License Amendment, the Company assumed responsibility from BCM for the filing, prosecution and maintenance of the patent rights licensed by the Company from BCM under the A&R License Agreement that are in common with the License Agreement. Further, BCM also transferred to the Company the right of enforcement against third parties for any suspected infringement of any claims in such patent rights or misuse, misappropriation, theft or breach of confidence of other proprietary rights.

Exclusive License Agreement with BCM

In November 2020, the Company signed a second License Agreement (the "Second License Agreement) with BCM, whereby the Company acquired a royalty-bearing, worldwide, exclusive license to BCM's rights in Subject Technology and related patent rights outside the field of viral infection (all fields other than those covered by the A&R License Agreement).

Unless earlier terminated, the Second License Agreement will expire on a country-by-country basis with respect to a product upon the later of (a) the expiration of the last to expire valid claim of a patent or patent application covering such product in such country or (b) 10 years after the first commercial sale of such product in such country, provided that the Second License Agreement shall not expire later than March 25, 2040. The Company may terminate the Second License Agreement in its entirety at any time for convenience upon

a certain number of days' written notice. BCM may terminate the Second License Agreement in its entirety for the Company's uncured material default.

Under the Second License Agreement, BCM transferred to the Company control of all filing, prosecution and maintenance of the patent rights licensed by the Company, and the Company is responsible for all related costs and expenses during the term of the Second License Agreement. BCM also transferred to the Company the right of enforcement against third parties for any suspected infringement of any claims in the patent rights or misuse, misappropriation, theft or breach of confidence of other proprietary rights. The Company also reimbursed BCM for costs and expenses (including reasonable legal fees and expenses) incurred prior to the effective date of the Second License Agreement with respect to the filing, prosecution and maintenance of the patent rights licensed by the Company, to the extent not already paid by the Company under the A&R License Agreement.

Under the Second License Agreement, the Company must use commercially reasonable efforts to develop and commercialize one or more products in certain countries. As partial consideration for the rights conveyed by BCM under the Second License Agreement, the Company paid BCM a non-refundable license fee of $125,000. During the term of the Second License Agreement, the Company is obligated to pay BCM a non-refundable annual license maintenance fee of (a) $20,000 for the first through fourth anniversary of the effective date of the Second License Agreement, and (b) $40,000 for the fifth anniversary of the effective date and continuing thereafter, but beginning with the fifth year, license maintenance fees are fully creditable against royalty revenue due in the applicable year. The Company is required to pay certain milestone payments upon the achievement of specified clinical, regulatory, and sales milestones. In the event that the Company is able to successfully develop, launch and commercialize multiple products under the Second License Agreement, total milestone payments could exceed $30.0 million. BCM is also eligible to receive tiered royalties at percentage rates ranging from less than 1% to the low single-digits, on net sales of any products that are commercialized by the Company or its sublicensees that incorporate, utilize or are made with the use of, the intellectual property licensed by the Company. To the extent the Company sublicenses its license rights under the Second License Agreement, BCM would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits.

Collaboration Agreement with BCM

In November 2020, the Company entered into a Research Collaboration Agreement (the "Research Agreement") with BCM, under which the Company agreed to pay BCM for performing certain research activities under the direction of Dr. Ann Leen commencing on January 1, 2021 and continuing for a three-year period thereafter. The Research Agreement requires the Company to make payments to BCM totaling approximately $6.0 million over the term of the Research Agreement. In August 2023, the Research Agreement was extended for an additional year, expiring December 31, 2024.

Collectively under the agreements above and for services provided by BCM the Company paid $2.0 million and $2.5 million during the years ended December 31, 2023 and 2022, respectively, and the payments were classified in research and development expense in the consolidated statements of operations and comprehensive loss.

CPRIT Grant

In August 2017, the Company was awarded a grant (the "CPRIT Grant") from the Cancer Prevention and Research Institute of Texas ("CPRIT"). The CPRIT Grant required that the Company grant CPRIT a non-commercial license to technology developed under the grant and pay CPRIT a share of revenue on sales of commercial products developed using CPRIT funds equal to low single digits of revenue until such time as CPRIT has been paid an aggregate amount equal to 400% of the grant award proceeds. No royalty payments were made under this license agreement during the years ended December 31, 2023 and 2022, respectively.

Redeemable Preferred Stock Redemption Agreement

In September 2018, the Company entered into a redeemable preferred stock redemption agreement, or Redemption Agreement, to redeem shares of our Series A1 convertible preferred stock held by certain investors, including executive officer Ann Leen, director and former executive officer Juan Vera and entities affiliated with director, Malcolm Brenner and former director, John Wilson (or their affiliates). Pursuant to the Redemption Agreement, for a period of 20 years from the date of the first commercial sale of Viralym-M (now posoleucel), the Company is obligated to make earnout payments to such investors on at least an annual basis. The earnout payments will be 10% of net sales of Viralym-M, which number will be reduced to a high single-digit percentage if certain events occur. Specifically, royalties due to third parties for the sale of Viralym-M are subtracted from the earnout payments due to the investors. Further, if the investors receive at least $50,000,000 in earnout payments from AlloVir during the three-year period after the first commercial sale of Viralym-M, the earnout payment percentage will be reduced.

9. Stockholder's Equity

On May 15, 2023, the Company filed a certificate of amendment to its amended and restated certificate of incorporation authorizing the Company to issue up to 300,000,000 shares of common stock at a par value of $0.0001 per share and 10,000,000 shares of preferred stock at a par value of $0.0001 per share. There were no shares of preferred stock issued or outstanding at December 31, 2023 and 2022.

On June 21, 2023, the Company entered into an underwriting agreement with J.P. Morgan Securities LLC, Morgan Stanley & Co. LLC and BoFA Securities, Inc., as the representatives of the several underwriters (the "Underwriters") relating to an underwritten public offering of 20,000,000 shares of its common stock at a public offering price of $3.75 per share, resulting in net proceeds of $70.2 million after deducting underwriting discounts and commissions of $4.5 million and offering costs of $0.3 million. Under the terms of the underwriting agreement, the Company granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 3,000,000 shares of its common stock at the same price per share as the shares, less underwriting discounts and commissions. On July 21, 2023, the Underwriters option expired.

On July 26, 2022, the Company entered into the Securities Purchase Agreement with certain investors for aggregate net proceeds of $126.4 million after deducting issuance costs of $0.2 million. Pursuant to the terms of the Securities Purchase Agreement, the Company agreed to issue and sell to the investors in a registered direct offering an aggregate of 27,458,095 shares of the Company's common stock, par value $0.0001 per share (the "Shares") at a purchase price of $4.61 per Share (the "Offering"). The Offering was made without an underwriter or a placement agent, and therefore, there were no underwriting discounts or commissions in connection with the offering.

The following is a summary of the rights and privileges of the holders of the Company's common stock at December 31, 2023 and 2022:

Voting Rights

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there are not any cumulative voting rights. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of shares of capital stock of the Company; however, the issuance of common stock may be subject to the vote of the holders of one or more series of preferred stock that may be required by terms of the Third Amended and Restated Certificate of Incorporation.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the Board out of legally available funds. At December 31, 2023, no cash dividends have been declared or paid.

Liquidation Preference

In the event of a liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all debts and other liabilities and the satisfaction of any liquidation preference granted to the then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that the Company may designate in the future.

The Company has reserved shares of common stock for issuance as follows:

	December 31,	
	2023	2022
Unvested restricted stock	3,254,863	2,239,106
Options to purchase common stock	10,439,751	7,922,797
Stock available for grant under the 2020 Stock Option and Grant Plan	4,182,461	4,253,680
Stock available for issuance under the 2020 Employee Stock Purchase Plan	480,059	454,302
Total	18,357,134	14,869,885

10. Stock-Based Compensation

Stock-Based Compensation Expense

Stock-based compensation expense was as follows:

(in thousands)	Years Ended December 31, 2023	2022
Research and development	$ 13,167	$ 14,014
General and administrative	27,612	27,301
Total stock-based compensation expense	$ 40,779	$ 41,315

2018 Equity Incentive Plan

The Company's 2018 Plan provided for the Company to issue restricted stock, restricted stock units, incentive stock options, and non-statutory stock options and other stock-based awards to employees, officers, members of the Board, consultants and advisors of the Company. The 2018 Plan was most recently amended in July 2020. The awards granted under this plan generally vest over a four-year period and have a 10-year contractual term.

At December 31, 2023, there was an aggregate of 64,042 shares of common stock issuable upon the exercise of outstanding options under the 2018 Plan and 6,616,772 shares of restricted common stock granted under the 2018 plan. No shares remain available for future issuance under the 2018 Plan. Any options or awards outstanding under the 2018 Plan remain outstanding and effective.

2020 Stock Option and Grant Plan

On July 2, 2020, the Company's Board of Directors adopted and in July 2020 the stockholders approved the 2020 Stock Option and Grant Plan (the "2020 Plan") which became effective on July 28, 2020, the date immediately prior to the date on which the registration statement related to the IPO was declared effective, and as a result no further awards were made under the 2018 Plan thereafter. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2020 Plan was 8,008,734 shares. The number of shares of our common stock reserved for issuance under the 2020 Plan shall be cumulatively increased on January 1, 2021 and each January 1 thereafter by 5% of the total number of shares of our common 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. On January 1, 2023, 4,663,403 shares were added to the number of available shares under the 2020 Plan. The awards granted under this plan generally vest over a four-year period and have a 10-year contractual term.

At December 31, 2023, there were an aggregate of 10,375,709 shares of common stock issuable upon the exercise of outstanding options under the 2020 Plan and 5,356,510 shares of restricted common stock granted under the 2020 Plan. There is an aggregate of 4,182,461 shares reserved for future issuance under the 2020 Plan.

Restricted Common Stock

The following table summarizes restricted common stock activity for the year ended December 31, 2023:

	Shares	Weighted Average Grant Date Fair Value
Unvested at January 1, 2023	2,239,106	$ 13.75
Granted	2,279,994	6.02
Forfeited	(342,732)	11.46
Vested	(921,505)	13.24
Unvested at December 31, 2023	3,254,863	$ 8.73

At December 31, 2023, there was $23.6 million of unrecognized stock-based compensation cost related to the restricted stock, which is expected to be recognized over a weighted average period of 2.20 years. The total fair value of restricted stock vested was $3.6 million and $14.2 million for the year ended December 31, 2023 and 2022, respectively.

Stock Options

The following table summarizes stock option activity (in thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Life	Aggregate Intrinsic Value
Options outstanding at January 1, 2023	7,922,797	$ 17.81	8.3	$ 786
Granted	3,779,342	6.24	—	57
Exercised	—	—	—	—
Forfeited	(1,262,388)	16.25	—	82
Options outstanding at December 31, 2023	10,439,751	$ 13.81	7.9	$ —
Options vested and exercisable at December 31, 2023	4,534,147	$ 18.86	7.2	$ —

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the common stock as of the end of the period.

The weighted average grant-date fair value of stock options granted during the year ended December 31, 2023 and 2022 was $4.88 per share and $5.61 per share, respectively. At December 31, 2023, there was $36.9 million of unrecognized stock-based compensation expense related to unvested stock options, which is being recognized over a period of 1.92 years.

The fair value was estimated on the date of grant using the Black-Scholes option-pricing model, with the following weighted-average assumptions:

	Years Ended December 31,	
	2023	2022
Expected term (in years)	6.11	6.07
Expected volatility	94%	90%
Risk-free interest rate	3.52%	2.00%
Expected dividend yield	—	—
Fair value of common stock	$ 6.24	$ 7.48

2020 Employee Stock Purchase Plan

In July 2020, the 2020 Employee Stock Purchase Plan (the "2020 ESPP") was adopted by the Board of Directors and approved by the stockholders. The purpose of the 2020 ESPP is to provide eligible employees of the Company and other designated companies, with opportunities to purchase shares of the Company's common stock, par value $0.0001 per share.

Initially, 611,354 shares of common stock in the aggregate were approved and reserved for this purpose. The number of shares of common stock reserved and available for issuance under the 2020 ESPP shall be cumulatively increased on January 1, 2021 and each January 1 thereafter by the least of (i) 1,222,707 shares of common stock, (ii) 1% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, and (iii) such number of shares of common stock as determined by the Administrator. On January 1, 2023, 160,000 shares were added to the number of available shares under the ESPP. At December 31, 2023, there was an aggregate of 480,059 shares reserved for future issuance under the ESPP.

The ESPP allows eligible employees to authorize payroll deductions of up to 15% of their base salary or wages up to $25,000 annually to be applied toward the purchase of shares of the Company's common stock on the last trading day of the offering period. Participating employees will purchase shares of the Company's common stock at a discount of up to 15% on the lesser of the closing price of the Company's common stock on the NASDAQ Global Market (i) on the first trading day of the offering period or (ii) the last day of any offering period. The Company utilizes the Black Scholes option pricing model to compute the fair market value of the shares and compensation expense is recognized over the offering period. Six-month offering periods commence each January 1 and July 1 during the term of the plan, with the administrator having the right to establish different offering periods.

Participation in the ESPP is voluntary. Eligible employees become participants in the ESPP by enrolling in the plan and authorizing payroll deductions. At the end of each offering period, accumulated payroll deductions are used to purchase the Company's shares at the discounted price. The Company makes no contributions to the ESPP. A participant may withdraw from the ESPP or suspend contributions to the ESPP. If the participant elects to withdraw during an offering period, all contributions are refunded as soon as

administratively practicable. If a participant elects to withdraw or suspend contributions, they will not be able to re-enroll in the current offering but may elect to participate in future offerings. The ESPP purchases only whole shares of the Company's common stock.

The Company issued 134,243 common shares under the ESPP during the year ended December 31, 2023, at an average price per share of $2.43. Cash received from purchases under the ESPP for the year ended December 31, 2023 and 2022 was $0.3 million and $0.5 million, respectively. The Company recognized $0.3 million and $0.2 million of compensation expense for the ESPP during the year ended December 31, 2023 and 2022, respectively.

11. Income Taxes

Income (loss) before provision for income taxes consisted of the following:

	Years Ended December 31,	
(in thousands)	2023	2022
Federal	(376,152)	(113,389)
Foreign	185,608	(55,586)
Loss before provision for income taxes	$ (190,544)	$ (168,975)

The provision for income taxes for the years ended December 31, 2023 and 2022 consisted of the following:

	Years Ended December 31,	
(in thousands)	2023	2022
Current income tax (benefit) expense:		
Federal	$ (136)	(246)
State	10	(19)
Foreign	—	—
Total current income tax benefit	(126)	(265)
Deferred income tax (benefit) expense:		
Federal	—	—
State	—	—
Foreign	—	—
Total deferred income tax benefit	—	—
Total income tax benefit	$ (126)	$ (265)

The Company's income tax benefit for the years ended December 31, 2023 and 2022 relating to federal, state and foreign tax jurisdictions differs from the amounts determined by applying the statutory federal income tax rate based on the following:

	Years Ended December 31,			
(in thousands)	2023		2022	
Benefit at the federal rate	$ (40,015)	21.0%	$ (35,472)	21.0%
Increase (decrease) resulting from:				
Foreign tax rate differential	(15,783)	8.3%	2,177	(1.3)%
State taxes, net of federal benefit	(9,514)	5.0%	(1,603)	0.9%
Change in valuation allowance	98,714	(51.8)%	35,406	(21.0)%
Intercompany note impairment	(34,615)	18.2%	—	—
Tax credits	(5,928)	3.1%	(6,992)	4.1%
Officer's compensation	177	(0.1)%	695	(0.4)%
Stock compensation	4,564	(2.4)%	4,637	(2.7)%
Impairment of intellectual property	3,003	(1.6)%	—	—
Permanent differences	79	0.0%	(182)	0.1%
Change in state tax law	384	(0.2)%	—	—
Other	(1,192)	0.6%	1,069	(0.6)%
Total income tax benefit	$ (126)	0.1%	$ (265)	0.1%

In 2021, the Company transferred intellectual property rights between tax jurisdictions, resulting in a deferred tax asset on the basis difference in the intangible assets. In addition, in connection with the transfer of the intellectual property the Company recorded intercompany notes between the parties. In December 2023, the Company determined that the intellectual property intangible assets and intercompany notes were impaired resulting in the recognition of income or loss in the respective jurisdiction.

Components of deferred income taxes consist of the following:

	December 31,	
(in thousands)	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	$ 54,081	$ 9,374
Tax credit carryforwards	19,378	12,374
Intangible assets	—	25,537
Intercompany note impairment	64,087	
Operating lease liabilities	6,348	8,074
Non-qualified stock compensation	15,435	12,017
Restricted stock compensation	680	235
Capitalization of R&D expenses	20,758	20,375
Other	676	1,661
Total deferred tax assets	181,443	89,647
Valuation allowance	(180,943)	(82,228)
Net deferred tax assets	$ 500	$ 7,419
Deferred tax liabilities:		
Operating lease right-of-use assets	(506)	(7,218)
Depreciation	4	(186)
Other	2	(15)
Total deferred tax liabilities	(500)	(7,419)
Net deferred tax asset (liability)	$ —	$ —

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At December 31, 2023 and 2022, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the accompanying consolidated balance sheets. For the year ended December 31, 2023, the valuation allowance for deferred tax assets increased by $98.7 million, which was principally due to increased deffered taxes for net operating losses and intercompany note impairment. For the year ended December 31, 2022, the valuation allowance for deferred tax assets increased by $35.4 million, which was principally due to net operating losses, tax credits, tax basis generated from the intellectual property transfer, and U.S. research and development expense capitalization.

At December 31, 2023 and 2022, the Company had unused federal net operating loss carryforwards of $38.9 million and $0, respectively. The federal net operating loss carryforwards have no expiration, and are limited in utilization to 80% of taxable income. The CARES Act temporarily allows the Company to carryback net operating losses arising in 2018, 2019 and 2020 to the five prior tax years. In addition, net operating losses generated in these years could fully offset prior year taxable income without the 80% of the taxable income limitation under the TCJA which was enacted on December 22, 2017. The Company has been generating losses since its inception, as such the net operating loss carryback provision under the CARES Act is not applicable to the Company.

At December 31, 2023 and 2022, the Company had unused state net operating loss carryforwards of $26.4 million and $3.6 million, respectively. The state net operating loss carryforwards expire in 2035.

At December 31, 2023 and 2022, the Company had unused foreign net operating loss carryforwards of $354.8 million and $72.9 million, respectively. The foreign net operating loss carryforwards have no expiration.

At December 31, 2023 and 2022, the Company had $11.7 million and $6.6 million of federal research and development tax credit carryforwards that may be available to offset future federal income taxes through 2040. Additionally, at December 31, 2023, the Company had a federal orphan drug credit (ODC) carryforward related to qualifying research of $6.0 million that will begin to expire

in 2041. At December 31, 2023 and 2022, the Company also had $2.1 million and $1.3 million of research and development tax credit carryforwards that may be available to offset future state income taxes in the state of Massachusetts through 2035.

Utilization of net operating loss and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development tax credit carryforwards that can be utilized annually to offset future taxable income and tax expense, respectively. The Company has completed several financings since its inception which may result in a change of control as defined in Section 382 of the Internal Revenue Code or could result in a change in control in the future.

The Company complies with the provisions of ASC 740 in accounting for its uncertain tax positions. ASC 740 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. At December 31, 2023 and 2022, the Company had no uncertain tax positions.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties in income tax expense. The Company had no accruals for interest and penalties at December 31, 2023 and 2022.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. The statute of limitations for assessment by the Internal Revenue Service and state tax authorities remains open for the tax years December 31, 2020 through December 31, 2023 as the Company was incorporated in September 2018. There are currently no federal, state or foreign income tax audits in progress. The resolution of tax matters is not expected to have a material effect on the Company's consolidated financial statements.

12. Net Loss per Share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company:

	Years Ended December 31,	
(in thousands, except share and per share data)	**2023**	**2022**
Numerator:		
Net loss – basic and diluted	$ (190,418)	$ (168,710)
Denominator:		
Weighted-average common shares outstanding – basic and diluted	104,057,220	76,654,856
Net loss per share – basic and diluted	$ (1.83)	$ (2.20)

Based on the amounts outstanding at December 31, 2023 and 2022, the Company excluded the following potential shares of common stock from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2023 and 2022, because including them would have had an anti-dilutive effect. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

	Years Ended December 31,	
	2023	**2022**
Options to purchase common stock	10,439,751	7,922,797
Unvested restricted stock	3,254,863	2,239,106

13. Commitments and Contingencies

Leases

The Company entered into a lease agreement and a sublease agreement for the lease of property in Waltham, Massachusetts (see Note 5 and Note 16).

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. On January 19, 2024, a purported stockholder of the Company filed a lawsuit, captioned Zerbato v. AlloVir, Inc. et al., No. 1:24-cv-10152 (D. Mass.), in Massachusetts federal court against the Company and two of its officers purportedly on behalf of a putative class of stockholders consisting of persons who purchased or otherwise acquired Company securities between March 22, 2022 and December 21, 2023, inclusive. The complaint purports to assert claims under Section 10(b) and 20(a) of the Securities Act of 1934, as amended, and the related regulations, alleging that the defendants made false and misleading statements and omissions to investors relating to the Company's three Phase 3 studies of posoleucel. The complaint seeks, among other things, damages, prejudgment and post-judgment interest, and attorneys' fees, expert fees and other costs. The Company intends to vigorously defend against the lawsuit. As the outcome is not presently determinable, any loss is neither probable nor reasonably estimable.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs and other third-party vendors for clinical trials and testing and manufacturing services, which can contain purchase commitments or other noncancelable obligations. Most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of services provided up to one year after the date of cancellation. The amount and timing of such payments are not known.

We may incur potential contingent payments upon our achievement of clinical, regulatory and commercial milestones, as applicable, or we may be required to make royalty payments under license and grant agreements we have entered into with various entities pursuant to which we have in-licensed certain intellectual property. Due to the uncertainty of the achievement and timing of the events requiring payment under these agreements, the amounts to be paid by us are not fixed or determinable at this time (see Note 8).

14. Related Party Transactions

In March 2020, the Company entered into a Management and Administrative Services Agreement with ElevateBio Technologies, Inc. that provides for ongoing services to the Company in areas such as information technology, human resources and administration management, and facilities. The Company is billed monthly for such services at cost, with mark-up for profit on specific services, but including reasonable allocations of employee benefits, facilities and other direct or fairly allocated indirect costs that relate to the associates providing the services. The agreement has an initial term of five years and will automatically renew for successive one year terms, unless earlier terminated under the terms of the agreement.

In May 2020, the Company entered into a Development and Manufacturing Services Agreement with ElevateBio BaseCamp, Inc. ("BaseCamp") pursuant to which BaseCamp provides products and services that are used in the Company's laboratory operations, including consulting services, project management services, quality control services and cGMP drug product manufacturing (see Note 5). The agreement will expire upon the later of (a) five years from the effective date of January 1, 2019 or (b) the completion of services under all work orders executed prior to the fifth anniversary of the effective date, unless earlier terminated under the terms of the agreement.

In August 2022, the Company made a $2.0 million prepayment to BaseCamp for future services.

The Company incurred $2.6 million and $3.5 million during the year ended December 31, 2023 and 2022, respectively, related to services provided to the Company by ElevateBio and affiliates. At December 31, 2023 and 2022, the Company owed ElevateBio and affiliates $0.3 million and $0.1 million, respectively and had prepaid expenses with ElevateBio and affiliates of $0 and $2.0 million, respectively.

In March 2023, the Company entered into a services agreement with Marker Therapeutics, Inc. ("Marker") pursuant to which Marker provides development services to the Company. Juan Vera, a current director and former executive officer of the Company, is co-founder, director and chief executive officer of Marker. In June 2023, CellReady LLC ("CellReady") acquired certain manufacturing assets previously owned by Marker, and inherited the service agreement that Allovir previously maintained with Marker. The Company incurred $0.5 million during the year ended December 31, 2023, under the agreement. At December 31, 2023, the Company owed CellReady $0.5 million.

Members of the Company's management and board of directors received consulting fees totaling $0.4 million and $0.5 million during the years ended December 31, 2023 and 2022, respectively.

15. Employee Benefit Plans

Effective January 1, 2019, the Company adopted a 401(k) Plan for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. The Company made matching contributions of $0.9 million and $0.8 million for the years ended December 31, 2023 and 2022, respectively.

16. Subsequent Events

In January 2024, the board of directors approved a reduction in the Company's workforce by approximately 95% of the Company's current employee base in order to reduce costs and preserve capital in light of the announcement on December 22, 2023 that the Company is discontinuing its three global Phase 3 posoleucel studies. This workforce reduction will take place primarily during the first quarter of 2024 and expected to be substantially completed by April 15, 2024. As a result of these actions, the Company expects to incur personnel-related restructuring charges, excluding bonuses accrued as of December 31, 2023, of approximately $10 million in connection with one-time employee termination cash expenditures, including severance and other benefits. The Company had previously granted certain of the terminated employees restricted stock units (“RSUs”) that vest in annual installments based on continued service to the Company, as well as options to purchase shares of the Company’s common stock that typically vest over a period of four years. In connection with the reduction in workforce, the Company agreed to accelerate the vesting of a portion of the RSUs that were unvested as of the employees’ termination dates.

In February 2024, the Company entered into a new SOW ("2024 SOW under the DMS Agreement") that terminated the 2022 SOW under the DMS Agreement with a third-party supplier (see Note 5), resulting in a decrease in lease payments of $5.7 million in 2024. In Q1 2024, the Company paid all remaining lease obligations of $2.9 million.

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in Registration Statement No. 333-258539 on Form S-3 and Registration Statement Nos. 333-269810, 333-262632, 333-253028 and 333-240259 on Form S-8 of our report dated March 15, 2024 relating to the financial statements of AlloVir, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2023.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

March 15, 2024

Exhibit 31.1

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

I, Diana Brainard, certify that:

1. I have reviewed this Annual Report on Form 10-K of AlloVir, 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(s) 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 13a-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(s) 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: March 15, 2024

By: /s/ Diana Brainard

Diana Brainard
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Vikas Sinha, certify that:

1. I have reviewed this Annual Report on Form 10-K of AlloVir, 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(s) 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 13a-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(s) 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: March 15, 2024

By: /s/ Vikas Sinha

Vikas Sinha
President, Chief Financial Officer and Director
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Annual Report of AlloVir, Inc. (the "Company") on Form 10-K for the period ending December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I 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 15(d) of the Securities Exchange Act of 1934; 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: March 15, 2024

By: /s/ Diana Brainard

Diana Brainard
Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 32.2

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 AlloVir, Inc. (the "Company") on Form 10-K for the period ending December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I 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 15(d) of the Securities Exchange Act of 1934; 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: March 15, 2024

By: /s/ Vikas Sinha

Vikas Sinha
President, Chief Financial Officer and Director
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 97

ALLOVIR, INC.

COMPENSATION RECOVERY POLICY

Adopted as of October 26, 2023

AlloVir, Inc., a Delaware corporation (the "Company"), has adopted a Compensation Recovery Policy (this "Policy") as described below.

1. Overview

The Policy sets forth the circumstances and procedures under which the Company shall recover Erroneously Awarded Compensation from Covered Persons (as defined below) in accordance with rules issued by the United States Securities and Exchange Commission (the "SEC") under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the Nasdaq Stock Market. Capitalized terms used and not otherwise defined herein shall have the meanings given in Section 3 below.

2. Compensation Recovery Requirement

In the event the Company is required to prepare a Financial Restatement, the Company shall recover reasonably promptly all Erroneously Awarded Compensation with respect to such Financial Restatement.

3. Definitions

a. "Applicable Recovery Period" means the three completed fiscal years immediately preceding the Restatement Date for a Financial Restatement. In addition, in the event the Company has changed its fiscal year: (i) any transition period of less than nine months occurring within or immediately following such three completed fiscal years shall also be part of such Applicable Recovery Period and (ii) any transition period of nine to 12 months will be deemed to be a completed fiscal year.

b. "Applicable Rules" means any rules or regulations adopted by the Exchange pursuant to Rule 10D-1 under the Exchange Act and any applicable rules or regulations adopted by the SEC pursuant to Section 10D of the Exchange Act.

c. "Board" means the Board of Directors of the Company.

d. "Committee" means the Compensation Committee of the Board or, in the absence of such committee, a majority of independent directors serving on the Board.

e. "Covered Person" means any Executive Officer and any other person designated by the Board or the Committee as being subject to this Policy. A person's status as a Covered Person with respect to Erroneously Awarded Compensation shall be determined as of the time of receipt of such Erroneously Awarded Compensation

regardless of the person's current role or status with the Company (e.g., if a person began service as an Executive Officer after the beginning of an Applicable Recovery Period, that person would not be considered a Covered Person with respect to Erroneously Awarded Compensation received before the person began service as an Executive Officer, but would be considered a Covered Person with respect to Erroneously Awarded Compensation received after the person began service as an Executive Officer where such person served as an Executive Officer at any time during the performance period for such Erroneously Awarded Compensation).

f. "Effective Date" means October 26, 2023.

g. "Erroneously Awarded Compensation" means the amount of any Incentive-Based Compensation received by a Covered Person on or after the Effective Date and during the Applicable Recovery Period that exceeds the amount that otherwise would have been received by the Covered Person had such compensation been determined based on the restated amounts in a Financial Restatement, computed without regard to any taxes paid. Calculation of Erroneously Awarded Compensation with respect to Incentive-Based Compensation based on stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in a Financial Restatement, shall be based on a reasonable estimate of the effect of the Financial Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was received, and the Company shall maintain documentation of the determination of such reasonable estimate and provide such documentation to the Exchange in accordance with the Applicable Rules. Incentive-Based Compensation is deemed received, earned, or vested when the Financial Reporting Measure is attained, not when the actual payment, grant, or vesting occurs.

h. "Exchange" means the Nasdaq Stock Market LLC.

i. An "Executive Officer" means any person who served the Company in any of the following roles at any time during the performance period applicable to Incentive-Based Compensation such person received during service in such role: the president, principal financial officer, principal accounting officer (or if there is no such accounting officer the controller), any vice president in charge of a principal business unit, division, or function (such as sales, administration, or finance), any other officer who performs a policy making function, or any other person who performs similar policy making functions for the Company. Executive officers of parents or subsidiaries of the Company may be deemed executive officers of the Company if they perform such policy making functions for the Company.

j. "Financial Reporting Measures" mean measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, any measures that are derived wholly or in part from such measures (including, for example, a non-GAAP financial measure), and stock price and total shareholder return.

k. "Incentive-Based Compensation" means any compensation provided, directly or indirectly, by the Company or any of its subsidiaries that is granted, earned, or vested based, in whole or in part, upon the attainment of a Financial Reporting Measure and any equity-based compensation provided by the Company or any of its subsidiaries, including, without limitation, stock options, restricted stock awards, restricted stock units and stock appreciation rights.

l. A "Financial Restatement" means a restatement of previously issued financial statements of the Company due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required restatement to correct an error in previously-issued financial statements that is material to the previously-issued financial statements or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period.

m. "Restatement Date" means, with respect to a Financial Restatement, the earlier to occur of: (i) the date the Board or the Audit Committee of the Board concludes, or reasonably should have concluded, that the Company is required to prepare the Financial Restatement or (ii) the date a court, regulator or other legally authorized body directs the Company to prepare the Financial Restatement.

4. Exception to Compensation Recovery Requirement

The Company may elect not to recover Erroneously Awarded Compensation pursuant to this Policy if the Committee determines that recovery would be impracticable, and one or more of the following conditions, together with any further requirements set forth in the Applicable Rules, are met: (i) the direct expense paid to a third party, including outside legal counsel, to assist in enforcing this Policy would exceed the amount to be recovered, and the Company has made a reasonable attempt to recover such Erroneously Awarded Compensation; or (ii) recovery would likely cause an otherwise tax-qualified retirement plan to fail to be so qualified under applicable regulations.

5. Tax Considerations

To the extent that, pursuant to this Policy, the Company is entitled to recover any Erroneously Awarded Compensation that is received by a Covered Person, the gross amount received (i.e., the amount the Covered Person received, or was entitled to receive, before any deductions for tax withholding or other payments) shall be returned by the Covered Person.

6. Method of Compensation Recovery

The Committee shall determine, in its sole discretion, the method for recovering Erroneously Awarded Compensation hereunder, which may include, without limitation, any one or more of the following:

a. requiring reimbursement of cash Incentive-Based Compensation previously paid;

b. seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer or other disposition of any equity-based awards;

c. cancelling or rescinding some or all outstanding vested or unvested equity-based awards;

d. adjusting or withholding from unpaid compensation or other set-off;

e. cancelling or offsetting against planned future grants of equity-based awards; and/or

f. any other method permitted by applicable law or contract.

Notwithstanding the foregoing, a Covered Person will be deemed to have satisfied such person's obligation to return Erroneously Awarded Compensation to the Company if such Erroneously Awarded Compensation is returned in the exact same form in which it was received; provided that equity withheld to satisfy tax obligations will be deemed to have been received in cash in an amount equal to the tax withholding payment made.

7. Policy Interpretation

This Policy shall be interpreted in a manner that is consistent with the Applicable Rules and any other applicable law. The Committee shall take into consideration any applicable interpretations and guidance of the SEC in interpreting this Policy, including, for example, in determining whether a financial restatement qualifies as a Financial Restatement hereunder. To the extent the Applicable Rules require recovery of Incentive-Based Compensation in additional circumstances besides those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive-Based Compensation to the fullest extent required by the Applicable Rules.

8. Policy Administration

This Policy shall be administered by the Committee. The Committee shall have such powers and authorities related to the administration of this Policy as are consistent with the governing documents of the Company and applicable law. The Committee shall have full power and authority to take, or direct the taking of, all actions and to make all determinations required or provided for under this Policy and shall have full power and authority to take, or direct the taking of, all such other actions and make all such other determinations not inconsistent with the

specific terms and provisions of this Policy that the Committee deems to be necessary or appropriate to the administration of this Policy. The interpretation and construction by the Committee of any provision of this Policy and all determinations made by the Committee under this policy shall be final, binding and conclusive.

9. Compensation Recovery Repayments not Subject to Indemnification

Notwithstanding anything to the contrary set forth in any agreement with, or the organizational documents of, the Company or any of its subsidiaries, Covered Persons are not entitled to indemnification for Erroneously Awarded Compensation or for any claim or losses arising out of or in any way related to Erroneously Awarded Compensation recovered under this Policy.

EXECUTIVE OFFICERS

Diana Brainard, M.D.
Chief Executive Officer

Vikas Sinha
President and Chief Financial Officer

Ann Leen, Ph.D.
Chief Scientific Officer

Edward Miller
General Counsel and Secretary

Brett Hagen
Chief Accounting Officer

BOARD OF DIRECTORS

David Hallal
Executive Director, AlloVir, Inc.
Co-Founder, Chairman and Chief Executive Officer, ElevateBio LLC

Jeffrey Bornstein
Managing Partner, Generation Capital Partners

Malcolm Brenner, M.D., Ph.D.
Co-Founder, AlloVir, Inc.
Founding Director, Center for Cell and Gene Therapy, Baylor College of Medicine

Derek Adams, Ph.D.
President and Chief Executive Officer, Stellular Bio, Inc.

Morana Jovan-Embiricos, Ph.D.
Managing Director, F2 Ventures

Juan F. Vera, M.D.
Co-Founder, AlloVir, Inc.
Chief Executive Officer, Marker Therapeutics, Inc.

Shawn Tomasello
Former Chief Commercial Officer, Kite Pharma, Inc.

Diana Brainard, M.D.
Chief Executive Officer, AlloVir, Inc.

Vikas Sinha
President and Chief Financial Officer, AlloVir, Inc.

CORPORATE INFORMATION

Corporate Headquarters
1100 Winter Street
Waltham, MA 02451

Transfer Agent
Computershare Trust Company, N.A.
250 Royall Street
Canton, MA 02021

Visit us on the web: www.allovir.com

Independent Registered Public Accounting Firm
Deloitte & Touche LLP
Boston, MA

Investor Relations
ir@allovir.com