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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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**

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

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

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

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

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

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

As of October 27, 2023, the registrant had 114,063,336 shares of common stock, $0.0001 par value per share, outstanding.

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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 are a late 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.
- Our business is highly dependent on our lead product candidate, posoleucel (previously referred to as Viralym-M or ALVR105), and we must complete clinical testing before we can seek regulatory approval and begin commercialization of any of our product candidates.
- 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 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 Quarterly Report on Form 10-Q, 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q are forward-looking statements, including but not limited to, statements about:

- the success, cost, timing and potential indications of our product development activities and clinical trials, including the ongoing and 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;
- 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;
- 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;
- our ability to successfully commercialize our product candidates, including posoleucel and ALVR106;
- 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 II, Item 1A of this Quarterly Report on Form 10-Q, if any, 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 Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q 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—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited)

ALLOVIR, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS
UNAUDITED

(in thousands, except share and per share amounts)	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 95,627	$ 106,092
Short-term investments	117,691	127,703
Interest receivable	234	157
Prepaid expenses and other current assets	5,892	7,100
Prepaid expenses to related party	575	2,000
Total current assets	220,019	243,052
Restricted cash	852	852
Other assets	1,425	612
Property and equipment, net	673	930
Operating lease right-of-use assets	25,343	31,633
Total assets	$ 248,312	$ 277,079
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,925	$ 3,004
Accrued expenses	15,924	13,985
Income tax payable	—	128
Operating lease liability, current	12,976	7,165
Amount due to related party	241	56
Total current liabilities	33,066	24,338
Operating lease liability, long-term	19,912	28,222
Total liabilities	$ 52,978	$ 52,560
Stockholders' equity:		
Preferred stock, $0.0001 par value: 10,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 0 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	—	—
Common stock, $0.0001 par value: 300,000,000 and 150,000,000 shares authorized at September 30, 2023 and December 31, 2022, respectively; 113,972,541 and 93,268,069 shares issued at September 30, 2023 and December 31, 2022, respectively; and 113,966,594 and 93,093,243 shares outstanding at September 30, 2023 and December 31, 2022, respectively	11	9
Additional paid-in capital	792,020	690,753
Accumulated other comprehensive loss	(200)	(468)
Accumulated deficit	(596,497)	(465,775)
Total stockholders' equity	195,334	224,519
Total liabilities and stockholders' equity	$ 248,312	$ 277,079

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

ALLOVIR, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
UNAUDITED

(in thousands, except share and per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 34,156	$ 30,004	$ 99,698	$ 90,450
General and administrative	12,805	12,946	37,797	40,318
Total operating expenses	46,961	42,950	137,495	130,768
Loss from operations	(46,961)	(42,950)	(137,495)	(130,768)
Total other income (loss), net:				
Interest income	1,522	668	4,362	978
Other income (loss), net	1,167	210	2,411	(634)
Loss before income taxes	(44,272)	(42,072)	(130,722)	(130,424)
Income tax expense	—	—	—	150
Net loss	$ (44,272)	$ (42,072)	$ (130,722)	$ (130,574)
Net loss per share — basic and diluted	$ (0.39)	$ (0.50)	$ (1.30)	$ (1.83)
Weighted-average common shares outstanding — basic and diluted	113,894,188	84,948,837	100,683,322	71,213,219
Comprehensive loss:				
Net loss	$ (44,272)	$ (42,072)	$ (130,722)	$ (130,574)
Other comprehensive income (loss), net of tax:				
Unrealized gain (loss) on available-for-sale securities	25	(119)	268	(408)
Total other comprehensive income (loss)	25	(119)	268	(408)
Comprehensive loss	$ (44,247)	$ (42,191)	$ (130,454)	$ (130,982)

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

ALLOVIR, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
UNAUDITED

(in thousands, except share amounts)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2021	63,565,886	$ 7	$ 522,479	$ (155)	$ (297,065)	$ 225,266
Stock-based compensation	—	—	10,467	—	—	10,467
Issuance of common stock, upon vesting of restricted stock	698,241	—	—	—	—	—
Unrealized loss on available-for-sale securities	—	—	—	(195)	—	(195)
Net loss	—	—	—	—	(43,863)	(43,863)
Balance at March 31, 2022	64,264,127	$ 7	$ 532,946	$ (350)	$ (340,928)	$ 191,675
Stock-based compensation	—	—	10,951	—	—	10,951
Issuance of common stock, upon vesting of restricted stock	450,619	—	—	—	—	—
Purchase of common stock under the 2020 Employee Stock Purchase Plan	73,357	—	244	—	—	244
Unrealized loss on available-for-sale securities	—	—	—	(94)	—	(94)
Net loss	—	—	—	—	(44,639)	(44,639)
Balance at June 30, 2022	64,788,103	$ 7	$ 544,141	$ (444)	$ (385,567)	$ 158,137
Stock-based compensation	—	—	10,855	—	—	10,855
Issuance of common stock, upon vesting of restricted stock	393,911	—	—	—	—	—
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	—	—	—	(119)	—	(119)
Net loss	—	—	—	—	(42,072)	(42,072)
Balance at September 30, 2022	92,640,109	$ 9	$ 681,419	$ (563)	$ (427,639)	$ 253,226

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

ALLOVIR, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
UNAUDITED

(in thousands, except share amounts)	Common Stock Shares	Common Stock Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2022	93,093,243	$ 9	$ 690,753	$ (468)	$ (465,775)	$ 224,519
Stock-based compensation	—	—	10,029	—	—	10,029
Issuance of common stock, upon vesting of restricted stock	334,747	—	—	—	—	—
Unrealized gain on available-for-sale securities	—	—	—	167	—	167
Net loss	—	—	—	—	(41,183)	(41,183)
Balance at March 31, 2023	93,427,990	$ 9	$ 700,782	$ (301)	$ (506,958)	$ 193,532
Stock-based compensation	—	—	10,288	—	—	10,288
Issuance of common stock, upon vesting of restricted stock	179,092	—	—	—	—	—
Purchase of common stock under the 2020 Employee Stock Purchase Plan	108,936	—	315	—	—	315
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	—	—	—	76	—	76
Net loss	—	—	—	—	(45,267)	(45,267)
Balance at June 30, 2023	113,716,018	$ 11	$ 781,552	$ (225)	$ (552,225)	$ 229,113
Stock-based compensation	—	—	10,468	—	—	10,468
Issuance of common stock, upon vesting of restricted stock	250,576	—	—	—	—	—
Unrealized gain on available-for-sale securities	—	—	—	25	—	25
Net loss	—	—	—	—	(44,272)	(44,272)
Balance at September 30, 2023	113,966,594	$ 11	$ 792,020	$ (200)	$ (596,497)	$ 195,334

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

ALLOVIR, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
UNAUDITED

(in thousands)	Nine Months Ended September 30, 2023	2022
Cash flows from operating activities		
Net loss	$ (130,722)	$ (130,574)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	257	637
Non-cash lease expense	3,790	834
Accretion of short-term investment discounts	(2,486)	(206)
Stock-based compensation expense	30,785	32,273
Changes in operating assets and liabilities:		
Interest receivable	(77)	(211)
Prepaid expenses and other current assets and prepaid expenses to related party	2,633	(1,862)
Other assets	(813)	367
Income tax payable	(128)	(853)
Accounts payable, accrued expenses and amount due to related party	3,045	(10,886)
Net cash used in operating activities	(93,716)	(110,481)
Cash flows from investing activities		
Purchase of short-term investments	(116,046)	(191,340)
Maturities of short-term investments	128,813	97,325
Net cash provided by (used in) investing activities	12,767	(94,015)
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	315	244
Net cash provided by financing activities	70,484	126,669
Net decrease in cash, cash equivalents, and restricted cash	(10,465)	(77,827)
Cash, cash equivalents, and restricted cash at beginning of period	106,944	202,513
Cash, cash equivalents, and restricted cash at end of period	$ 96,479	$ 124,686
Non-cash investing and financing activities		
Unrealized gain (loss) on available-for-sale securities	$ 268	$ (408)
Deferred offering costs included in accounts payable and accrued expenses	$ 46	$ —
Reduction of right-of-use asset and operating lease liability due to modification and remeasurement	$ —	$ (5,506)
Purchase of property and equipment included in accounts payable and accrued expenses	$ —	$ 32
Supplemental disclosure of cash flows		
Income taxes paid, net of refunds	$ 351	$ 1,003

	Nine Months Ended September 30, 2023	2022
Cash and cash equivalents	$ 95,627	$ 123,834
Restricted cash	852	852
Total cash, cash equivalents, and restricted cash	$ 96,479	$ 124,686

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

1. Nature of the Business

AlloVir, Inc. (“AlloVir” or “the Company”, formerly known as ViraCyte, Inc.) is a leading late clinical-stage 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 is developing three innovative, allogeneic, off-the-shelf VST therapy candidates targeting 11 different devastating viruses. The Company's lead product, 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. The Company believes that posoleucel has the potential to fundamentally transform the treatment landscape for transplant patients by substantially reducing or preventing disease morbidity and mortality, thereby dramatically improving patient outcomes.

Posoleucel is being studied in three ongoing Phase 3 registrational trials for three distinct indications - the prevention of clinically significant infections from multiple viruses, the treatment of virus-associated hemorrhagic cystitis, or HC, and the treatment of AdV infections – all in allogeneic hematopoietic cell transplant, or HCT, patients who are at high risk for life-threatening viral infections from the six viruses targeted by posoleucel. Data readouts from all three trials are expected in the second half of 2024. In addition to the ongoing Phase 3 registrational studies, posoleucel has been studied in a Phase 2 proof-of-concept, or POC, study for the treatment of BK viremia in kidney transplant patients. Positive topline results from this study were released in February 2023. This is the first study of posoleucel in solid organ transplant, or SOT, patients, and the results of this trial will inform next steps for this potential indication as well as the Company’s broader SOT strategy.

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. In the preclinical space, the Company is developing ALVR107 to treat hepatitis B, or HBV, infected cells and with the aim of curing chronic HBV infection. Preclinical and IND-enabling studies of ALVR107 to treat and cure HBV were completed in 2022 to support advancement into a POC study after completion of the posoleucel Phase 3 registrational studies.

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.

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 condensed consolidated financial statements are issued.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, 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. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate

personnel and infrastructure and extensive compliance and reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Through September 30, 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 $44.3 million and $42.1 million for the three months ended September 30, 2023 and 2022, respectively, and $130.7 million and $130.6 million for the nine months ended September 30, 2023 and 2022, respectively. In addition, at September 30, 2023, the Company had an accumulated deficit of $596.5 million. The Company expects to continue to generate operating losses for the foreseeable future.

The Company believes that its $213.3 million of cash, cash equivalents and short-term investments held at September 30, 2023 is sufficient to fund planned operations for at least twelve months from the date that these condensed consolidated financial statements are issued.

COVID-19 Considerations

The development of product candidates could be disrupted and materially adversely affected in the future by a prolonged public health epidemic, pandemic or outbreak of an infectious disease, such as the COVID-19 pandemic. Although the immediate impacts of COVID-19 have receded, the COVID-19 pandemic impacted the global economy and the Company's operations, including the interruption of preclinical and clinical trial activities and potential interruption to the Company's supply chain. For example, the COVID-19 pandemic has delayed clinical trials.

The Company will continue to assess the impact COVID-19, including any resurgences, may have on its ability to advance the testing, development and manufacturing of drug candidates, including as a result of adverse impacts on the research sites, service providers, vendors, or suppliers on whom the Company relies on, or to raise financing to support the development of our drug candidates. No assurances can be given that this analysis will enable the Company to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or this sector in particular. The Company cannot presently predict the scope of any potential business shutdowns or disruptions, but if the Company or any of the third parties on whom it relies on or with whom it conducts business, were to experience shutdowns or other business disruptions, the Company's ability to conduct business in the manner and on the timelines presently planned could be materially and adversely impacted.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2022, and notes thereto, which are included in the Company's Annual Report on Form 10-K that was filed with the Securities and Exchange Commission, or the SEC, on February 15, 2023. Since the date of those financial statements, there have been no material changes to the Company's significant accounting policies except as described below.

Interim Financial Information

The accompanying condensed consolidated balance sheet at September 30, 2023, and the condensed consolidated statements of operations and comprehensive loss, statements of changes in stockholders' equity for the three and nine months ended September 30, 2023 and 2022 and the condensed consolidated statements of cash flows for the nine months ended September 30, 2023 and 2022 are unaudited. The condensed consolidated interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments necessary for the fair presentation of the Company's financial position at September 30, 2023 and the results of its operations for the three and nine months ended September 30, 2023 and 2022 and its cash flows for the nine months ended September 30, 2023 and 2022. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2023 and 2022 are also unaudited. The results for the three and nine months ended September 30, 2023 are not necessarily indicative of results to be expected for the year ending December 31, 2023 or for any other subsequent interim period.

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.

Since December 31, 2022, there have been no new accounting pronouncements adopted by the Company or issued by FASB that are applicable to the Company, except as noted below.

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 condensed consolidated financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

None.

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 condensed consolidated balance sheets:

	September 30, 2023			
(in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government treasury securities	$ 115,256	$ 2	$ (63)	$ 115,195
Marketable securities:				
Corporate and agency bonds	2,500	—	(4)	2,496
Totals	$ 117,756	$ 2	$ (67)	$ 117,691

	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 condensed 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 September 30, 2023 and December 31, 2022, all investments had contractual maturities within one year.

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

	September 30, 2023			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Cash equivalents:				
Money market fund	$ 22,097	$ —	$ —	$ 22,097
Totals	$ 22,097	$ —	$ —	$ 22,097
Short-term investments:				
U.S. government treasury securities	$ 115,195	$ —	$ —	$ 115,195
Marketable securities:				
Corporate and agency bonds	—	2,496	—	$ 2,496
Totals	$ 115,195	$ 2,496	$ —	$ 117,691

	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 nine months ended September 30, 2023 and the year ended December 31, 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 SOW under the DMS Agreement ("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. 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 ROU asset and lease liability of $14.7 million.

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. The agreement also provided a $3.1 million tenant improvement allowance which is to be reimbursed by the landlord over the duration of the first two years of the Waltham leases. At September 30, 2023, $0.9 million of the tenant improvement allowance has been used. 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. At September 30, 2023, the Company has no reasonable certainty that this option to extend will be exercised.

Maturities of operating lease liabilities at September 30, 2023 are as follows (in thousands):

2023 (remaining 3 months)	6,103
2024	11,531
2025	3,228
2026	3,306
2027	3,385
Thereafter	9,677
Total lease payments	37,230
Less: interest	(4,342)
Total lease liability	$ 32,888
Lease liability – current	$ 12,976
Lease liability – long-term	$ 19,912

Total lease costs were $2.6 million and $1.2 million for the three months ended September 30, 2023 and 2022, respectively, and $7.7 million and $4.1 million for the nine months ended September 30, 2023 and 2022, respectively. Cash paid for operating leases was $0.8 million and $1.1 million for the three months ended September 30, 2023 and 2022, respectively, and $3.9 million and $3.2 million for the nine months ended September 30, 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 $0.2 million and $1.5 million for the three months ended September 30, 2023 and 2022, respectively, and $0.9 million and $3.6 million for the nine months ended September 30, 2023 and 2022, respectively. The weighted average remaining lease term was 6.37 years and 6.93 years at September 30, 2023 and December 31, 2022, respectively. The weighted average discount rate was 6.23% at September 30, 2023 and December 31, 2022.

6. Accrued Expenses

Accrued expenses consisted of the following:

(in thousands)	September 30, 2023	December 31, 2022
Employee compensation and benefits	$ 5,251	$ 6,416
Professional fees	977	559
Research and development	5,253	5,678
Process development and manufacturing costs	3,979	504
Other	464	828
Total accrued expenses	$ 15,924	$ 13,985

7. 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 September 30, 2023 and December 31, 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.

The Company has reserved shares of common stock for issuance as follows:

	September 30, 2023	December 31, 2022
Options to purchase common stock	10,445,312	7,922,797
Unvested restricted stock	3,410,391	2,239,106
Stock available for grant under the 2020 Stock Option and Grant Plan	4,178,462	4,253,680
Stock available for issuance under the 2020 Employee Stock Purchase Plan	505,366	454,302
Total	18,539,531	14,869,885

8. Stock-Based Compensation

Stock-Based Compensation Expense

Stock-based compensation expense was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Research and development	$ 3,254	$ 3,890	$ 10,191	$ 11,122
General and administrative	7,214	6,965	20,594	21,151
Total stock-based compensation expense	$ 10,468	$ 10,855	$ 30,785	$ 32,273

2018 Equity Incentive Plan

At September 30, 2023, there was an aggregate of 64,042 shares of common stock issuable upon the exercise of outstanding options under the Company's 2018 Equity Incentive Plan, or 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

At September 30, 2023, there was an aggregate of 10,381,270 shares of common stock issuable upon the exercise of outstanding options under the Company's 2020 Stock Option and Grant Plan, or the 2020 Plan, and 5,330,610 shares of restricted common stock granted under the 2020 Plan. There is an aggregate of 4,178,462 shares reserved for future issuance under the 2020 Plan.

Restricted Common Stock

The following table summarizes restricted common stock activity for the nine months ended September 30, 2023:

	Shares	Weighted Average Grant Date Fair Value
Unvested at January 1, 2023	2,239,106	$ 13.75
Granted	2,254,094	6.06
Forfeited	(318,394)	11.36
Vested	(764,415)	12.59
Unvested at September 30, 2023	3,410,391	$ 9.16

At September 30, 2023, there was $27.2 million of unrecognized stock-based compensation cost related to the restricted stock, which is expected to be recognized over a weighted average period of 2.39 years.

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 (in years)	Aggregate Intrinsic Value
Options outstanding at January 1, 2023	7,922,797	$ 17.81	8.30	$ 786
Granted	3,731,242	6.30	—	—
Exercised	—	—	—	—
Forfeited	(1,208,727)	16.38	—	—
Options outstanding at September 30, 2023	10,445,312	$ 13.86	8.19	$ —
Options vested and exercisable at September 30, 2023	4,114,133	$ 18.99	7.40	$ —

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 nine months ended September 30, 2023 and 2022 was $4.92 per share and $5.62 per share, respectively. At September 30, 2023, there was $43.8 million of unrecognized stock-based compensation expense related to unvested stock options, which is being recognized over a period of 2.08 years.

The fair value was estimated on the date of grant using the Black-Scholes option-pricing model, with the following weighted-average assumptions:

	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2023
Expected term (in years)	6.09	6.11
Expected volatility	94.36%	94.48%
Risk-free interest rate	4.01%	3.51%
Expected dividend yield	—	—
Fair value of common stock	$ 3.24	$ 6.30

2020 Employee Stock Purchase Plan

The Company issued 108,936 shares of common stock under the 2020 Employee Stock Purchase Plan (the "ESPP") during the nine months ended September 30, 2023 at an average price per share of $2.89. Cash received from purchases under the ESPP for the nine months ended September 30, 2023 and 2022 were $0.3 million and $0.2 million, respectively. The Company recognized $0.3 million and $0.2 million of compensation expense for the ESPP during the nine months ended September 30, 2023 and 2022, respectively.

At September 30, 2023, there was an aggregate of 505,366 shares reserved for future issuance under the ESPP.

9. Income Taxes

The Company's income tax provision is computed based on the federal statutory rate, the average state statutory rates, net of the related federal benefit, and foreign statutory rates. For the three months ended September 30, 2023 and 2022, the Company did not record income tax expense. For the nine months ended September 30, 2023 and 2022, the Company recorded income tax expense of $0 and $0.2 million, respectively.

The Company's estimate of the realizability of the deferred tax asset is dependent on estimates of projected future levels of taxable income. In consideration of historical losses and in analyzing future taxable income levels, the Company considered all evidence currently available, both positive and negative, and has not recognized deferred tax assets.

10. 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:

(in thousands, except share and per share data)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Numerator:				
Net loss – basic and diluted	$ (44,272)	$ (42,072)	$ (130,722)	$ (130,574)
Denominator:				
Weighted-average common shares outstanding – basic and diluted	113,894,188	84,948,837	100,683,322	71,213,219
Net loss per share – basic and diluted	$ (0.39)	$ (0.50)	$ (1.30)	$ (1.83)

Based on the amounts outstanding at September 30, 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 three and nine months ended September 30, 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.

	September 30, 2023	September 30, 2022
Options to purchase common stock	10,445,312	8,499,509
Unvested restricted stock	3,410,391	2,746,971

11. 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. 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 $1.0 million and $0.6 million during the three months ended September 30, 2023 and 2022, respectively, and $1.6 million and $2.7 million during the nine months ended September 30, 2023 and 2022, respectively, related to services provided to the Company by ElevateBio and affiliates. At September 30, 2023 and December 31, 2022, the Company owed ElevateBio and affiliates $0 and $0.1 million, respectively and had prepaid expenses with ElevateBio and affiliates of $0.6 million 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. The Company incurred $0.2 million and $0.2 million during the three and nine months ended September 30, 2023, respectively, under the agreement. At September 30, 2023 and December 31, 2022, the Company owed Marker $0.2 million and $0, respectively.

Members of the Company’s management and board of directors received consulting fees totaling $0.1 million and $0.1 million during the three months ended September 30, 2023 and 2022, respectively, and $0.3 million and $0.4 million during the nine months ended September 30, 2023 and 2022, respectively.

Item 2. 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 unaudited condensed consolidated financial statements and related notes appearing in Part I, Item I of this Quarterly Report on Form 10-Q and with our audited consolidated financial statements and notes thereto for the year ended December 31, 2022, included in our Annual Report on Form 10-K that was filed on February 15, 2023 with the U.S. Securities and Exchange Commission, or the SEC.

Some of the information contained in this discussion and analysis or set forth elsewhere in this report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, 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. You should carefully read the section titled "Risk Factors" set forth in Part II, Item 1A of this Quarterly Report on Form 10-Q to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Special Note Regarding Forward-Looking Statements." You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

Overview

We are a leading late clinical-stage 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. We are developing three innovative, allogeneic, off-the-shelf VST therapy candidates targeting 11 different devastating viruses. Our lead product, 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. We believe posoleucel has the potential to fundamentally transform the treatment landscape for transplant patients by substantially reducing or preventing disease morbidity and mortality, thereby dramatically improving patient outcomes.

Posoleucel is being studied in three ongoing Phase 3 registrational trials for three distinct indications - the prevention of clinically significant infections from multiple viruses, the treatment of virus-associated hemorrhagic cystitis, or HC, and the treatment of AdV infections – all in allogeneic hematopoietic cell transplant, or HCT, patients who are at high risk for life-threatening viral infections from the six viruses targeted by posoleucel. Data readouts from all three trials are expected in the second half of 2024. In addition to the ongoing Phase 3 registrational studies, posoleucel has been studied in a Phase 2 POC study for the treatment of BK viremia in kidney transplant patients. Positive topline results from this study were reported in February 2023. This is the first study of posoleucel in SOT patients, and the results of this trial will inform next steps for this potential indication as well as our broader SOT strategy.

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. In the preclinical space, we are developing ALVR107 designed to target hepatitis B, or HBV, infected cells and with the aim of curing chronic HBV infection. Preclinical and IND-enabling studies of ALVR107 to treat and cure HBV were completed in 2022 to support advancement into a POC study after completion of the posoleucel Phase 3 studies.

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 September 30, 2023, no sales had been made pursuant to the ATM Program.

We have incurred significant operating losses since inception, including net losses of $44.3 million and $130.7 for the three and nine months ended September 30, 2023, respectively. As of September 30, 2023, we had an accumulated deficit of $596.5 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 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.

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 September 30, 2023, we had cash, cash equivalents and short-term investments of $213.3 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. 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. See "—Liquidity and Capital Resources."

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.

The successful development of our product candidates is highly uncertain. We plan to increase our research and development expenses for the foreseeable future as we continue the development of our product candidates and manufacturing processes and conduct discovery and research activities for our clinical programs. We cannot determine with certainty the timing of initiation, the duration or the completion costs of current or future clinical trials of our product candidates due to the inherently unpredictable nature of preclinical

and clinical development. Clinical development timelines, the probability of success and development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates to pursue and how much funding to direct to each product candidate on an ongoing basis in response to the results of ongoing and future clinical trials, regulatory developments and our ongoing assessments as to each product candidate's commercial potential. We will need to raise substantial additional capital in the future. Our clinical development costs are expected to increase significantly with our ongoing clinical trials. We anticipate that our expenses will increase substantially, particularly due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- 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.

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.

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 expense

Income tax expense consists of current income tax expense which is expected to be payable for the current year.

Results of Operations

Comparison of the three months ended September 30, 2023 and 2022

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

	Three Months Ended September 30,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 34,156	$ 30,004	$ 4,152
General and administrative	12,805	12,946	(141)
Total operating expenses	46,961	42,950	4,011
Loss from operations	(46,961)	(42,950)	(4,011)
Total other income (loss), net:			
Interest income	1,522	668	854
Other income (loss), net	1,167	210	957
Loss before income taxes	(44,272)	(42,072)	(2,200)
Income tax expense	—	—	—
Net loss	$ (44,272)	$ (42,072)	$ (2,200)

Research and Development Expenses

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

	Three Months Ended September 30,		
	2023	2022	Change
Direct research and development expenses by program:			
posoleucel	$ 20,770	$ 14,469	$ 6,301
ALVR106	375	870	(495)
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	11,434	12,237	(803)
Other expenses	1,577	2,428	(851)
Total research and development expenses	$ 34,156	$ 30,004	$ 4,152

Research and development expenses were $34.2 million for the three months ended September 30, 2023, compared to $30.0 million for the three months ended September 30, 2022. The increase of $4.2 million was primarily due to:

- a $6.3 million increase in costs related to the development of posoleucel, our most advanced product candidate, primarily due to an increase in costs related to the outsourcing of manufacturing of $3.8 million and the development of clinical trials of $2.5 million;
- a $0.5 million decrease in costs related to the development of ALVR106, primarily due to a reduction in costs related to the development of clinical trials of $0.4 million and the outsourcing of manufacturing of $0.1 million; and
- a $0.8 million decrease in consulting and personnel-related costs, including stock-based compensation expense.

General and Administrative Expenses

General and administrative expenses were consistent at $12.8 million for the three months ended September 30, 2023, compared to $12.9 million for the three months ended September 30, 2022.

Total Other Income (Loss), Net

Total other income (loss), net was $2.7 million for the three months ended September 30, 2023, compared to $0.9 million for the three months ended September 30, 2022. The increase of $1.8 million is primarily attributable to an increase of $1.0 million in accretion of discounts on short-term investments and an increase of $0.9 million in interest income.

Comparison of the nine months ended September 30, 2023 and 2022

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

	Nine Months Ended September 30,		
	2023	2022	Change
Operating expenses:			
Research and development	$ 99,698	$ 90,450	$ 9,248
General and administrative	37,797	40,318	(2,521)
Total operating expenses	137,495	130,768	6,727
Loss from operations	(137,495)	(130,768)	(6,727)
Total other income (loss), net:			
Interest income	4,362	978	3,384
Other income (loss), net	2,411	(634)	3,045
Loss before income taxes	(130,722)	(130,424)	(298)
Income tax expense	—	150	(150)
Net loss	$ (130,722)	$ (130,574)	$ (148)

Research and Development Expenses

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

	Nine Months Ended September 30,		
	2023	2022	Change
Direct research and development expenses by program:			
posoleucel	$ 58,303	$ 44,201	$ 14,102
ALVR106	1,128	3,278	(2,150)
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	34,831	36,746	(1,915)
Other expenses	5,436	6,225	(789)
Total research and development expenses	$ 99,698	$ 90,450	$ 9,248

Research and development expenses were $99.7 million for the nine months ended September 30, 2023, compared to $90.5 million for the nine months ended September 30, 2022. The increase of $9.2 million was primarily due to:

- a $14.1 million increase in costs related to the development of posoleucel, our most advanced product candidate, primarily due to an increase in costs related the development of clinical trials of $7.3 million and the outsourcing of manufacturing of $6.8 million;
- a $2.2 million decrease in costs related to the development of ALVR106, primarily due to a reduction in costs related to the outsourcing of manufacturing of $1.1 million and the development of clinical trials of $1.0 million; and
- a $1.9 million decrease in personnel expenses, including stock-based compensation, primarily due to a decrease in consulting costs of $1.8 million.

General and Administrative Expenses

General and administrative expenses were $37.8 million for the nine months ended September 30, 2023, compared to $40.3 million for the nine months ended September 30, 2022. The decrease of $2.5 million primarily consisted of a decrease of $1.2 million in consulting and personnel expenses, including stock-based compensation, and a decrease of $1.1 million in insurance related costs.

Total Other Income (Loss), Net

Total other income (loss), net was $6.8 million for the nine months ended September 30, 2023, compared to $0.3 million for the nine months ended September 30, 2022. The increase of $6.4 million is primarily attributable to an increase of $3.4 million in interest income, an increase of $2.3 million in accretion of discounts on short-term investments, and a decrease of $0.7 million in foreign exchange losses.

Liquidity and Capital Resources

Sources of Liquidity

At September 30, 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.

On August 6, 2021, we filed the Registration Statement with the SEC and simultaneously entered into a sales agreement with SVB Leerink LLC, as sales agent, for the ATM Program. 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. As of September 30, 2023, no sales had been made pursuant to the ATM Program.

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 September 30, 2023, our cash, cash equivalents and short-term investments were $213.3 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. 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 to incur significant expenses and operating losses for the foreseeable future as we 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.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the amount of our working capital requirements. Our future capital requirements will 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 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 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.

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 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):

	Nine Months Ended September 30,	
	2023	2022
	(in thousands)	
Net cash used in operating activities	$ (93,716)	$ (110,481)
Net cash provided by (used in) investing activities	12,767	(94,015)
Net cash provided by financing activities	70,484	126,669
Net decrease in cash, cash equivalents, and restricted cash	$ (10,465)	$ (77,827)

Operating Activities

Net cash used in operating activities was $93.7 million for the nine months ended September 30, 2023, reflecting a net loss of $130.7 million, partially offset by non-cash charges of $32.3 million. Non-cash charges primarily consist of stock compensation expense of $30.8 million. The change in our net operating assets and liabilities of $4.7 million was primarily due to an increase of $3.0 million in accounts payable, accrued expenses and amount due to related party and a decrease of $2.6 million in prepaid expenses and other current assets and prepaid expenses to related party, offset by an increase in other assets of $0.8 million.

Net cash used in operating activities was $110.5 million for the nine months ended September 30, 2022, reflecting a net loss of $130.6 million, partially offset by non-cash charges of $33.5 million. The non-cash charges primarily consist of stock compensation expense of $32.3 million. The change in our net operating assets and liabilities of $(13.4) million was primarily due to a decrease of $10.9 million in accounts payable, accrued expenses and amount due to related party, and an increase of $1.9 million in prepaid expenses and other current assets and prepaid expenses to related party.

The $16.8 million decrease in cash used in operating activities for the nine months ended September 30, 2023 compared to the nine months ended September 30, 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 $12.8 million for the nine months ended September 30, 2023, which was primarily due to investment maturities of $128.8 million, partially offset by the purchase of investments of $116.0 million.

Net cash used in investing activities was $94.0 million for the nine months ended September 30, 2022, which was primarily due to the purchase of investments of $191.3 million, partially offset by investment maturities of $97.3 million.

Financing Activities

Net cash provided by financing activities was $70.5 million for the nine months ended September 30, 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 $126.7 million for the nine months ended September 30, 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

During the nine months ended September 30, 2023, there were no material changes to our contractual obligations and commitments from those described under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ended December 31, 2022.

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of our unaudited interim condensed 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 condensed 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. There have been no significant changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations," included in our Annual Report on Form 10-K for the year ended December 31, 2022.

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 condensed 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 recent issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 4. 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-(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 September 30, 2023. Based on the evaluation of our disclosure controls and procedures as of September 30, 2023, our Chief Executive Officer and our Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

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 Quarterly Report on Form 10-Q that materially affected, or are 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.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become subject to arbitration, litigation or claims arising in the ordinary course of business. We are not currently a party to any material arbitration or legal proceedings. The results of any future claims or proceedings cannot be predicted with certainty, and regardless of the outcome, litigation can have an adverse impact on us because of defense and litigation costs, diversion of management resources, and other factors.

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 Quarterly Report on Form 10-Q, 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 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. 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. 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. In July 2020, the Investigational New Drug, or IND that Baylor College of Medicine, or BCM, submitted for ALVR109 was placed on clinical hold for safety concerns related to the quality of ancillary reagents unique to ALVR109. The FDA subsequently lifted this clinical hold and cleared the IND for ALVR109 but there can be no assurance that the FDA or comparable foreign regulatory authorities will not put clinical trials of any of our product candidates on clinical hold in the future. 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. 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, including our Phase 3 pivotal and Phase 2 proof-of-concept clinical trials of posoleucel, will generate adequate data to demonstrate the efficacy and safety of any of our product candidates. 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 we do not know whether the 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.

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.

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" in our Annual Report on Form 10-K for the year ended December 31, 2022.

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. 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 U.S. 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.

Our business is highly dependent on our lead product candidate, posoleucel, and 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” in our Annual Report on Form 10-K for the year ended December 31, 2022.

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. The Inflation Reduction Act of 2022, or IRA includes several provisions that may impact our business to varying degrees, including provisions that reduce the out-of-pocket spending cap for Medicare Part D beneficiaries from $7,050 to $2,000 starting in 2025, thereby effectively eliminating the coverage gap; impose new manufacturer financial liability on certain drugs under Medicare Part D, allow the U.S. government to negotiate Medicare Part B and Part D price caps for certain high-cost drugs and biologics without generic or biosimilar competition; require companies to pay rebates to Medicare for certain drug prices that increase faster than inflation; and delay until January 1, 2032 the implementation of the HHS rebate rule that would have limited the fees that pharmacy benefit managers can charge. 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 effects of the IRA on our business and the healthcare industry in general is not yet known.

In addition, 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.

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" in our Annual Report on Form 10-K for the year ended December 31, 2022.

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. HIPAA mandates the reporting of certain breaches of individually identifiable health 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. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA security regulations.

In addition, certain states 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, California recently enacted the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA will require 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 commenced enforcement actions against violators beginning July 1, 2020. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact our business activities. Further, a new California privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020 to amend and expand the CCPA. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). We will continue to monitor developments related to the CCPA, as amended and anticipate additional costs and expenses associated with compliance. The uncertainty surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information.

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 jurisdictions around the world continue to propose new 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.

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.

We may need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2023, we had 114 employees. As our development and commercialization plans and strategies develop, and as we begin operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. In particular, we may need to add substantial additional personnel and other resources to support our development and potential commercialization of our product candidates. As our development and commercialization plans and strategies continue to develop, or as a result of any future acquisitions, our need for additional managerial, operational, manufacturing, sales, marketing, financial and other resources will increase. Our management, personnel and systems currently in place may not be adequate to support this future growth. 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.

As our operations expand, we will also need to manage additional relationships with various strategic partners, suppliers and other third parties. Our future financial performance and our ability to commercialize our product candidates 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 preclinical and 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 growing our company.

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, 2022, we reported U.S. federal and state net operating loss carryforwards of approximately $0 million and $3.6 million, respectively, federal and state research and development tax credit carryforwards of $6.6 million and $1.3 million, respectively, and federal orphan drug credit carryforwards of $4.8 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, 2022, we reported foreign net operating loss carryforwards of $72.9 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. If we were to be sued, it 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 late 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 $168.7 million and $172.0 million for the years ended December 31, 2022 and 2021, respectively. As of September 30, 2023, we had an accumulated deficit of $596.5 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:

- continue to conduct 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;

- 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. We expect to continue to spend substantial amounts of capital to continue 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.

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, ALVR109 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, ALVR109 and other product candidates we may develop;
- if approved, the costs of commercialization activities for posoleucel for any approved indications, or ALVR106, ALVR109 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, ALVR109 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 $213.3 million as of September 30, 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.

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.

We are currently manufacturing our posoleucel and ALVR106 VSTs at an external cGMP CMO, and we primarily rely on a single contract testing laboratory for each drug product release test. We are also utilizing 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 are, and expect to remain, dependent on third parties to conduct our ongoing clinical trials and 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 (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 ongoing, planned 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.

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 66% of our common stock as of September 30, 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 ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, 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 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

(a) Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of AlloVir, Inc. (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 (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 AlloVir, Inc. (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	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-239698) filed on July 23, 2020).
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.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page for the Company's Quarterly Report on Form 10-Q has been formatted in Inline XBRL and contained in Exhibit 101

* Filed herewith.

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

† Schedules 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 U.S. Securities and Exchange Commission upon request.

SIGNATURES

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

AlloVir, Inc.

Date: November 2, 2023

By: /s/ Diana Brainard

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

Date: November 2, 2023

By: /s/ Vikas Sinha

Vikas Sinha
President, Chief Financial Officer and Director
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 31.1

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

I, Diana Brainard, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 2, 2023

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 Quarterly Report on Form 10-Q 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: November 2, 2023

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 Quarterly Report of AlloVir, Inc. (the "Company") on Form 10-Q for the period ending September 30, 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: November 2, 2023

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 Quarterly Report of AlloVir, Inc. (the "Company") on Form 10-Q for the period ending September 30, 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: November 2, 2023

By: /s/ Vikas Sinha

Vikas Sinha
President, Chief Financial Officer and Director
(Principal Financial Officer and Principal Accounting Officer)