

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

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(State or other jurisdiction of
incorporation or organization)**139 Main Street, Suite 500****Cambridge, MA**

(Address of principal executive offices)

83-1971007(I.R.S. Employer
Identification No.)**02142**

(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 Market

Securities registered pursuant to Section 12(g) of the Act: **None**Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES NO Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES NO Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (\$232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES NO

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

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company Emerging growth company If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. 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 June 30, 2020, the last day of the Registrant's most recently completed second fiscal quarter, there was no public market for the Registrant's common stock. The Registrant's common stock began trading on The Nasdaq Global Market on July 30, 2020. The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Global Market on February 2, 2021, was \$1,286,188,221.08. In determining the market value of non-affiliate common stock, shares of the Registrant's common stock beneficially owned by officers, directors and affiliates have been excluded. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of Registrant's Common Stock, par value \$0.0001 per share, outstanding as of February 2, 2021 was 65,106,873.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Proxy Statement for the registrant's 2021 Annual Meeting of Stockholders, or the Proxy Statement, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the Registrant's fiscal year end of December 31, 2020, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

	<u>Page</u>
<u>SUMMARY OF MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS</u>	1
<u>SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS</u>	2
<u>PART I</u>	4
Item 1. <u>Business</u>	4
Item 1A. <u>Risk Factors</u>	60
Item 1B. <u>Unresolved Staff Comments</u>	104
Item 2. <u>Properties</u>	104
Item 3. <u>Legal Proceedings</u>	104
Item 4. <u>Mine Safety Disclosures</u>	104
<u>PART II</u>	105
Item 5. <u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	105
Item 6. <u>Selected Financial Data</u>	105
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	106
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	118
Item 8. <u>Financial Statements and Supplementary Data</u>	118
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	118
Item 9A. <u>Controls and Procedures</u>	118
Item 9B. <u>Other Information</u>	118
<u>PART III</u>	119
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	119
Item 11. <u>Executive Compensation</u>	119
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	119
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	119
Item 14. <u>Principal Accounting Fees and Services</u>	119
<u>PART IV</u>	120
Item 15. <u>Exhibits, Financial Statement Schedules</u>	120
Item 16. <u>Form 10-K Summary</u>	122

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:

- Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic, in regions where third parties for which we rely, as in 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.
- 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, Viralym-M, 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-VST cell therapies. Delays in process performance qualification to validate the drug product manufacturing process could delay regulatory approvals, our development plans and thereby limit our ability to generate revenues.
- We are highly dependent on our key personnel and anticipate hiring new key personnel. If we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- The trading price of our common stock may be volatile.

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the success, cost, timing and potential indications of our product development activities and clinical trials, including the ongoing and future clinical trials of Viralym-M, ALVR106 and ALVR109;
- the timing of our planned Investigational New Drug (IND) submissions to the FDA for our product candidates, including ALVR106, ALVR109, ALVR107 and ALVR108;
- the timing of the initiation, enrollment and completion of planned clinical trials;
- our plans to research, develop and commercialize our product candidates, including Viralym-M, ALVR106, ALVR109, ALVR107 and ALVR108;
- 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 Viralym-M and ALVR106 or any other future product or product candidate, including under the Development and Manufacturing Services Agreement with ElevateBio BaseCamp, Inc.;
- 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 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 the COVID-19 pandemic, 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 Viralym-M, ALVR106 and ALVR109;
- the rate and degree of market acceptance of our product candidates, including Viralym-M, ALVR106 and ALVR109;
- 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 JOBS Act;
- our financial performance;
- the impact of laws and regulations;
- developments and projections relating to our competitors or our industry;

- the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and our ability to operate our business without infringing on the intellectual property rights of others.

In some cases, you can identify forward-looking statements by the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “predict,” “project,” “potential,” “should,” “will,” or “would,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

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

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

PART I

Item 1. Business.

Overview

We are a 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. To date, we have generated five innovative, allogeneic, off-the-shelf VST therapy candidates targeting 12 different devastating viruses. The most advanced is Viralym-M for which we have initiated a pivotal trial for the treatment of virus-associated hemorrhagic cystitis and POC clinical trials for multi-virus prevention in HSCT and BKV in kidney transplant.

Our lead product candidate, Viralym-M, is a multi-VST therapy targeting five viruses: BK virus, or BKV, cytomegalovirus, or CMV, adenovirus, or AdV, Epstein-Barr virus, or EBV, and human herpesvirus 6, or HHV-6. We are initially focusing the development of Viralym-M in immunocompromised allogeneic hematopoietic stem cell transplant, or HSCT, and solid organ transplant, or SOT, patients who are at high risk for life-threatening viral infections from the five viruses targeted by Viralym-M. In our Phase 2 proof-of-concept trial in 58 allogeneic HSCT patients with one or more treatment-refractory infections who were treated with Viralym-M, 93% achieved a clinical response.

Viralym-M 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. To fully explore the clinical benefit of Viralym-M, we plan to have up to a total of three Phase 3 pivotal and three Phase 2 proof-of-concept trials in clinical development by the end of 2021 for the treatment and prevention of life-threatening viral diseases in pediatric and/or adult patients, each representing a potential meaningful commercial opportunity. To this end three of these clinical trials have already been initiated, one in virus-associated hemorrhagic cystitis in HSCT patients, one in multi-virus prevention in HSCT patients and one for the treatment of BKV in Kidney Transplant patients and up to 3 additional studies are planned to be initiated later this year.

Based on the data generated from our Phase 2 proof-of-concept trial and the critical medical need, Viralym-M has been granted PRImity MEdicines, or PRIME, designation by the European Medicines Agency, or the EMA, for the treatment of serious infections caused by its five targeted viruses in HSCT patients. Moreover, Viralym-M was granted a Regenerative Medicine Advanced Therapy, or RMAT, designation by the U.S. Food and Drug Administration, or the FDA, for the treatment of hemorrhagic cystitis, or HC, caused by BKV in adults and children following allogeneic HSCT. Viralym-M was one of the first seven investigational therapies to receive both PRIME and RMAT designations. While these designations may not lead to a faster development process and do not increase the likelihood that a product candidate will receive approval from the FDA or EMA, we expect that PRIME and RMAT designations will result in increased EMA and FDA interactions to support our development efforts and may enable an expedited regulatory review process. In addition, the EMA's Committee for Orphan Medical Products granted orphan medicinal product designation to Viralym-M for all five targeted viruses in HSCT patients.

In clinical trials conducted to date, we have treated over 275 allogeneic HSCT patients with either single or multi-virus targeted allogeneic VSTs and our product candidates have been generally well-tolerated and have been associated with clinical benefit as indicated by the high response rate demonstrated in immunocompromised patients with drug-refractory infections and diseases. We believe that our allogeneic, off-the-shelf VSTs can benefit patients with other conditions characterized by T-cell deficiencies who are at high risk for life-threatening viral diseases, including immunocompromised cancer patients, the elderly and young children with immature immune systems. We are advancing a pipeline of VST therapies for delivery to individuals with compromised immune systems and those who are at high risk, or suffering from, the life-threatening consequences of viral diseases.

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

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

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

- ALVR106 is our second multi-virus-targeted off-the-shelf VST product candidate that we developed to target devastating respiratory diseases caused by respiratory syncytial virus, or RSV, influenza, parainfluenza virus, or PIV, and human metapneumovirus, or hMPV. Our Investigational New Drug, or IND, application with the FDA for ALVR106 was cleared in the fourth quarter of 2020, and the POC clinical trial is expected to initiate in the upcoming 2021 respiratory virus season.
- ALVR109 is an allogeneic, off-the-shelf single virus-targeted cell therapy designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19. ALVR109 is being developed to arrest the progression of COVID-19 by eradicating SARS-CoV-2 virus-infected cells. In its capacity as trial sponsor, Baylor College of Medicine, or BCM, initiated the POC clinical trial in the fourth quarter of 2020 with topline data expected in the second half of 2021. This trial is actively recruiting and ongoing.
- We are also advancing ALVR107 designed to target hepatitis B, or HBV, infected cells and treat chronic HBV infections and ALVR108 to treat human herpesvirus-8, or HHV-8, associated diseases including Kaposi Sarcoma, or KS, primary effusion lymphoma, or PEL, and multicentric Castleman's disease, or MCD. We plan to complete pre-clinical IND enabling studies for ALVR107 and ALVR108 in the second half of 2021.

If approved, we believe Viralym-M has a large global market opportunity to treat and prevent devastating viral diseases. Based on the established epidemiology of our target indications, we estimate the addressable transplant patient population for Viralym-M will increase from 81,000 HSCT and SOT patients in 2018 to approximately 97,000 HSCT and SOT patients annually in 2025. We believe transplant patients represent one segment of the large number of immunocompromised patients suffering from devastating viral infections who could potentially benefit from Viralym-M.

As an ElevateBio LLC affiliate, we are able to leverage ElevateBio's expertise to rapidly and efficiently manufacture VST therapies for clinical trials and commercialization. ElevateBio has established Elevate BaseCamp, Inc., or BaseCamp, a centralized cell and gene therapy manufacturing facility dedicated to the production of products for its affiliated companies. Currently, we are working with ElevateBio to manufacture our clinical trial supply at an external contract manufacturing organization, or CMO and we also plan to add ElevateBio BaseCamp to our manufacturing network by 2021.

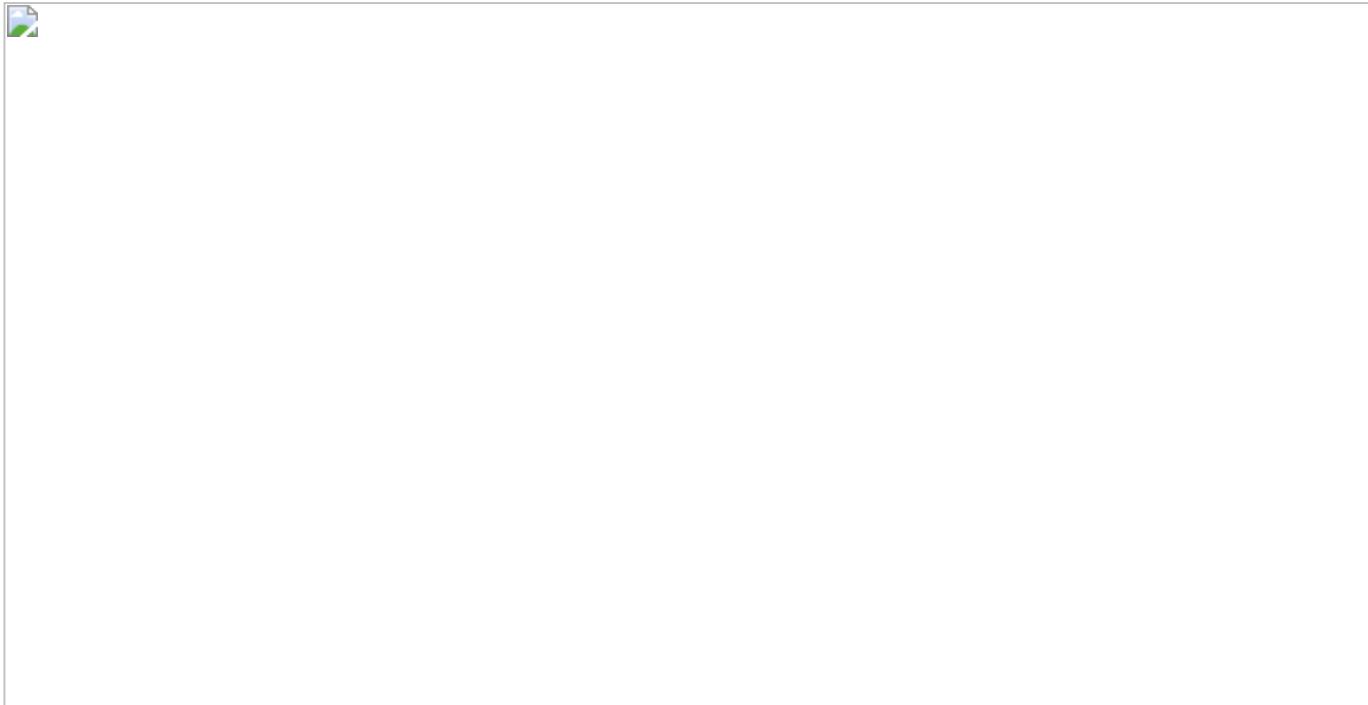
Our management team has significant experience in successfully advancing products from early stage discovery through commercialization. In particular, our Chief Executive Officer, David Hallal, is a proven 30-year veteran in the biopharmaceutical industry, having grown and operated several successful biotechnology companies. During his 10 year tenure at Alexion Pharmaceuticals, when Alexion grew from a pre-commercial stage to join the S&P 500, he served as Chief Executive Officer, Chief Operating Officer and Chief Commercial Officer and he led the pipeline expansion from a single-product to multi-product company. Prior to Alexion, David spent nearly 20 years at Amgen, Biogen, and Eyetech in executive and senior leadership roles. David also serves as Chairman and CEO of ElevateBio, an Independent Chairman of Scholar Rock (SRRK) and iTeos Therapeutics (ITOS) as well as an Independent Director of Seer (SEER).

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

To date, we have raised \$156.9 million in aggregate gross proceeds through private financings and \$317.7 million in aggregate gross proceeds through our IPO, which closed in August 2020.

Our Pipeline

We are advancing a pipeline of five allogeneic off-the-shelf VST therapy candidates targeting 12 different viruses to treat and prevent life-threatening viral diseases. For each of these pipeline therapies, we have global development and commercialization rights. The chart below summarizes key information about our programs.



- **Viralym-M (ALVR105).** An allogeneic, off-the-shelf VST therapy candidate targeting five common viruses: BKV, CMV, AdV, EBV and HHV-6, which can lead to devastating viral disease in the allogeneic HSCT population. In our Phase 2 proof-of-concept trial, 93% of allogeneic HSCT patients with infections from one or more of the target viruses and who previously failed or were intolerant to conventional antiviral treatments achieved a clinical response when treated with Viralym-M therapy. Given that it is multi-virus-targeted VST product candidate, Viralym-M has multiple potential applications. To this end three clinical trials have already been initiated, one in virus-associated hemorrhagic cystitis in HSCT patients, one in multi-virus prevention in HSCT patients and one in the treatment of BKV in Kidney Transplant patients and up to three additional studies are planned to be initiated later this year. The initiated trials are actively recruiting and ongoing.
- **ALVR106.** An allogeneic, off-the-shelf VST therapy candidate developed to target devastating diseases caused by four respiratory viruses: RSV, influenza, PIV, and hMPV. We submitted an IND to the FDA for ALVR106 and received clearance in the fourth quarter of 2020. We anticipate initiating the POC clinical trial in the 2021 respiratory virus season.
- **ALVR109.** An allogeneic, off-the-shelf VST therapy candidate designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19. ALVR109 is being developed to arrest the progression of COVID-19 by eradicating SARS-CoV-2 virus-infected cells. The IND application for ALVR109 was cleared by the FDA in the third quarter of 2020 and the trial initiated in the fourth quarter of 2020 with topline data expected in the second half of 2021. This trial is actively recruiting and ongoing.
- **ALVR107.** An allogeneic, off-the-shelf VST therapy candidate designed to target HBV infected cells and treat patients with chronic HBV infections. We plan to complete pre-clinical IND enabling studies for ALVR107 for the treatment of HBV in the second half of 2021.
- **ALVR108.** An allogeneic, off-the-shelf VST therapy candidate designed to treat HHV8-associated diseases, including KS, PEL, or MCD. We plan to complete pre-clinical IND enabling studies for ALVR108 for the treatment of HHV-8 in the second half of 2021.

Our Strategy

Our goal is to extend our leadership position in the development of allogeneic, off-the-shelf VST cell therapies to serve patients at risk of the life-threatening consequences of severe viral diseases. To achieve this, we are pursuing the following strategies:

- **Accelerate Viralym-M through pivotal and proof-of-concept trials for six indications with no FDA-or EMA-approved or effective treatment options.** By targeting five devastating viral pathogens, we believe that Viralym-M has the potential to fundamentally transform the care of HSCT and SOT patients, as well as other individuals at high risk for opportunistic viral infections, by substantially reducing or preventing disease morbidity and dramatically improving patient outcomes. Our initial Phase 3 pivotal trial will assess Viralym-M for the treatment of patients with virus-associated hemorrhagic cystitis, or HC, following allogeneic HSCT. We initiated 2 Phase 2 proof-of-concept trials (currently on-going) and plan to initiate up to two additional Phase 3 trials for the treatment and prevention of life-threatening viral diseases.
- **Capitalize on our allogeneic VST platform to advance four additional highly innovative therapies targeting seven life-threatening viruses.** We believe that ALVR106 and ALVR109 have the potential to transform the treatment of respiratory viruses and substantially reduce the severity of respiratory infections while improving patient outcomes. ALVR106 will be developed in HSCT patients suffering from respiratory viral infections, with the goal to extend to other high-risk patient populations, such as immunocompromised cancer patients, the very young and the elderly. We developed ALVR109, an allogeneic, off-the-shelf SARS-CoV-2 targeted VST therapy candidate, for administration to COVID-19 patients who are at high risk for disease progression. In addition, we are advancing ALVR107 to treat chronic HBV infections and ALVR108 to treat HHV-8 associated diseases.
- **Further strengthen our leadership position as the innovator of VST therapies through continuous pipeline expansion.** Our highly efficient and versatile off-the-shelf VST therapy platform allows us to profile viruses and rapidly develop novel therapies for existing and emergent life-threatening viral infections and serve the large number of patients with devastating viral diseases. For example, we rapidly initiated the development of and progression into the clinic of a SARS-CoV-2 specific VST therapy candidate, ALVR109, in response to the COVID-19 pandemic. We intend to leverage this versatility to potentially address a broad spectrum of patients who could benefit from “off-the-shelf” VST therapies, including other individuals with compromised immune systems and those who are at high risk for the life-threatening consequences of viral diseases.
- **Leverage our differentiated, proprietary and versatile process to rapidly and efficiently manufacture our VST therapy candidates.** We have developed an efficient, reliable and scalable manufacturing process for our allogeneic, off-the-shelf VST therapy candidates. We also plan to leverage the substantial cell therapy manufacturing expertise and state-of-the-art facility of ElevateBio to expand internal capabilities for our growing global manufacturing network. We will leverage Cytokin™ and Cytomatch™, our proprietary algorithms for donor selection and VST therapy matching, to efficiently build our global supply chain to serve a growing number of patients that could benefit from our highly innovative off-the-shelf ready-to-use VST therapy candidates.
- **Build a fully integrated global VST therapy company.** We intend to continue building unparalleled bench-to-bedside capabilities to discover, develop, manufacture, and commercialize our highly innovative off-the-shelf VST therapy candidates, if approved, to serve a large number of patients suffering from the life-threatening consequences of viral diseases. Initially, to launch our late clinical stage therapies for the treatment of transplant patients, we will establish a focused commercial infrastructure targeting high-volume transplant centers globally. As we eventually progress to serve non-transplant patients at high-risk for the life-threatening consequences of viral diseases, we will expand our global commercial capabilities.

The Immune System and the Role of T-Cells

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

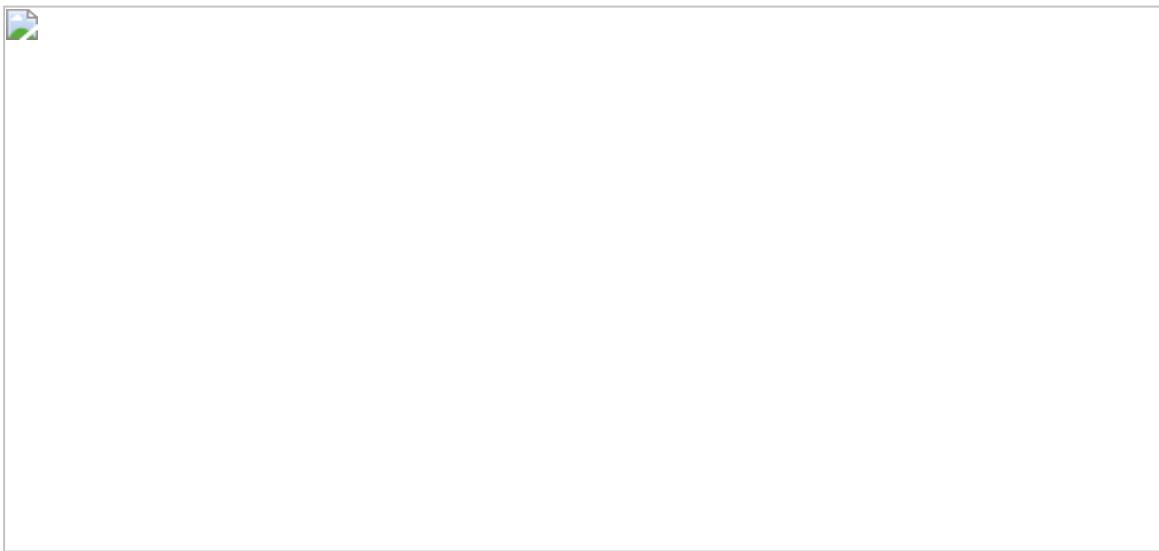


Figure 1. T-cells play a central role in response to viral infection

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

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

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

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

Transplantation and Immunosuppression

There are two major types of transplant procedures: HSCTs and SOTs. In each procedure, the immune system of the patient is suppressed or eliminated to prevent rejection of the transplanted cells or organs. In the case of HSCT, this immunocompromised state is typically temporary and resolves once the transplanted donor stem cells begin to replenish the cells of the immune system. In SOT, most patients require a high dose of immunosuppressive drugs for the first six months post-transplant and some degree of immunosuppressive treatment for the rest of their lives.

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

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

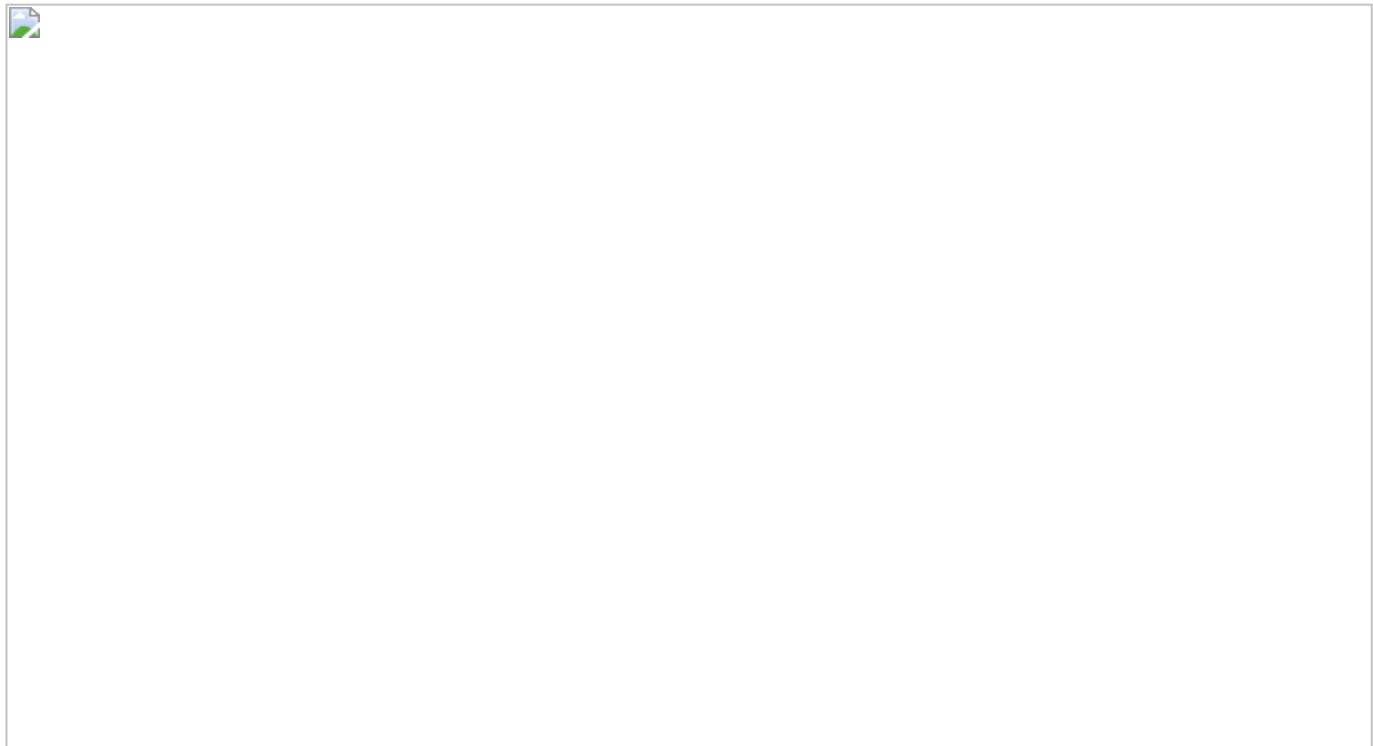
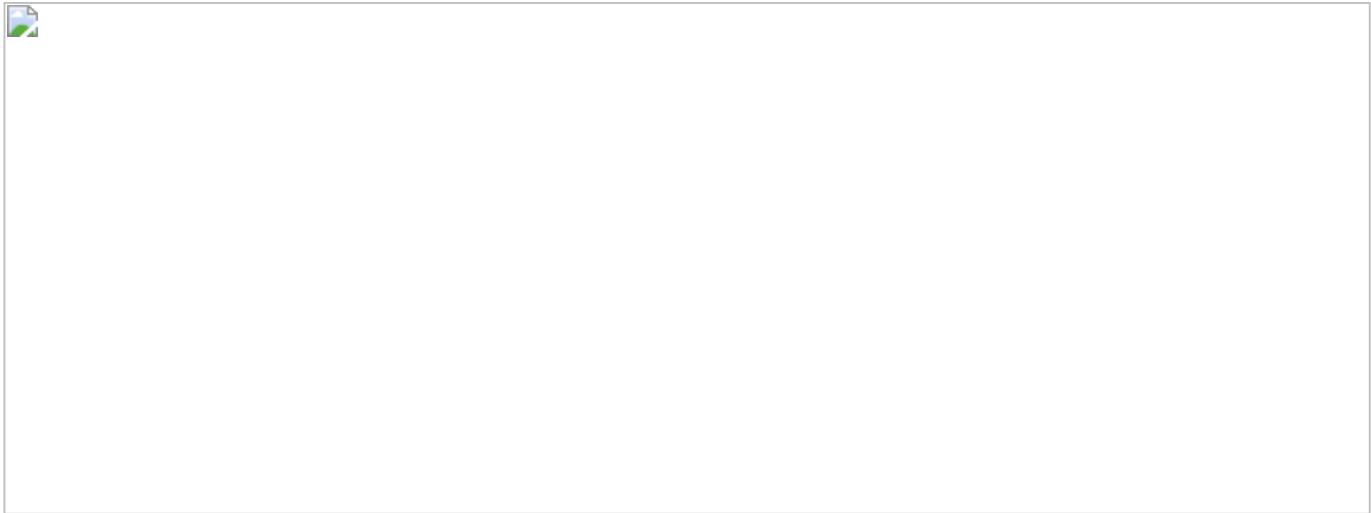


Figure 2. Approximately 90% of patients undergoing allogeneic HSCT have at least one viral infection and 62% have more than one.

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



BKV in Kidney Transplant and CMV in SOT Patients Lead to Decreased Graft Survival Despite Standard of Care

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

Limitations of Current Therapies for Immunocompromised Patients

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

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

In contrast, the adoptive transfer of *ex vivo* expanded VSTs to HSCT patients has generated promising preliminary disease outcome measures and safety data in treating a range of viral diseases in clinical trials. We designed an approach whereby VSTs could be prospectively generated from healthy, third-party donors expressing common HLA polymorphisms who were seropositive for all of the targeted viruses. These VSTs were prepared by stimulating peripheral blood mononuclear cells, or PBMCs, with viral antigens followed by *ex vivo* expansion and cryopreservation to enable utilization when needed by patients. We then clinically assessed whether such allogeneic VSTs, when administered as a partially HLA-matched off-the-shelf therapy could still provide clinical benefit in a safe manner. We have treated over 275 allogeneic HSCT patients with either single or multi-virus targeted allogeneic VSTs. Of these patients, 159 were infused with allogeneic VSTs generated from the same donor who donated the allogeneic stem cells, while 118 of these patients were infused with allogeneic VSTs generated from third-party donors. These off-the-shelf VSTs have been generally well-tolerated and were associated with clinical benefit as indicated by the high response rate demonstrated in immunocompromised patients with drug-refractory infections and diseases.

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

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



Figure 3: Adoptive transfer of off-the-shelf VSTs kill virus-infected cells and restore virus-specific T-cell immunity

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

Using our versatile and robust off-the-shelf VST platform, we are able to rapidly generate VST therapies for the treatment of a spectrum of viral diseases. This is demonstrated by our pipeline of five innovative, allogeneic off-the-shelf VST therapy candidates targeting both multi-virus (Viralym-M and ALVR106) and single virus indications (ALVR109, ALVR107 and ALVR108). Our portfolio not only showcases our potential to target multiple devastating viral diseases, but also highlights our ability to rapidly respond to emerging viruses, as evidenced by our COVID-19 program, and extend allogeneic off-the-shelf VST therapies beyond transplant patients in order to treat others at high risk of developing viral diseases.

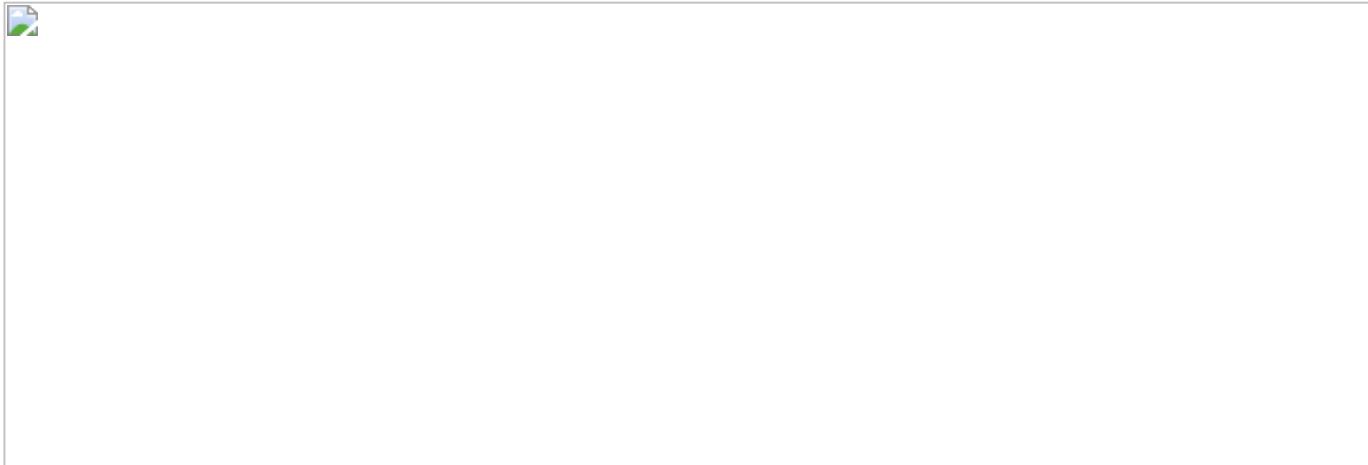


Figure 4. AlloVir's versatile off-the-shelf VST manufacturing platform

Our Proprietary Allogeneic VST Therapy Process

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

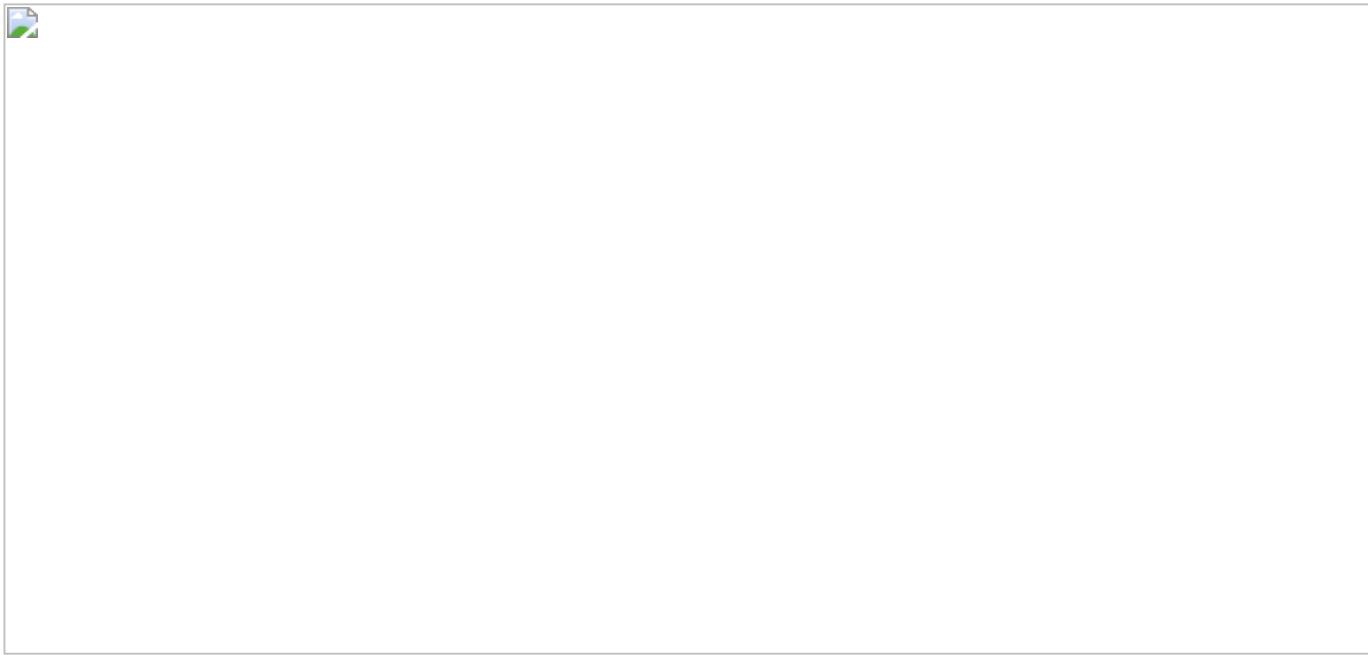


Figure 5. Key advantages of AlloVir's patented, highly efficient and industrialized VST platform

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

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

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

Donor Selection—CytokinTM

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

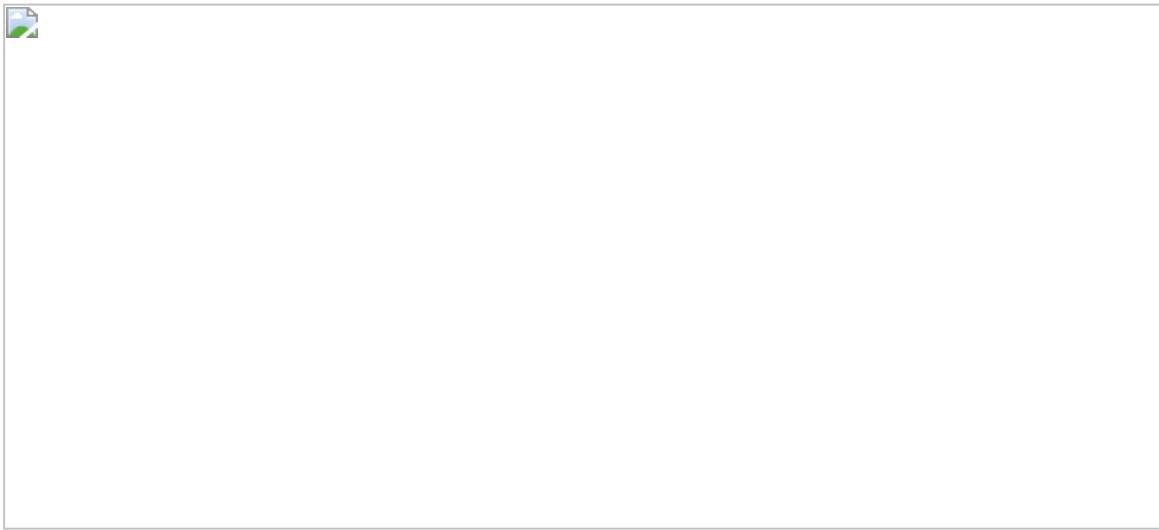


Figure 6. Implementing the CytokinTM algorithm to efficiently select donors from whom to generate mini-banks of VSTs

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

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

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

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

To facilitate drug supply for our proposed clinical trials, we are currently manufacturing our Viralym-M and ALVR106 VSTs at an external cGMP CMO and ALVR109 at an academic cGMP facility. However, as an ElevateBio LLC affiliate, we are able to leverage ElevateBio's expertise to rapidly and efficiently manufacture VST therapies both for clinical trials and commercialization. In fact, ElevateBio has established Elevate BaseCamp, Inc., or BaseCamp, a centralized cell and gene therapy manufacturing facility dedicated to the production of products for its affiliated companies. Therefore, we also plan to add ElevateBio BaseCamp to our manufacturing network in 2021.

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

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

The final component of our highly efficient and industrialized process relates to the clinical use of our allogeneic off-the-shelf VST therapy. The Cytomatch™ algorithm guides the selection of the VST line for patient treatment. VST therapies for infusion are chosen based on the level of HLA matching between patient and VST cell line, with two HLA allele matches set as a minimum threshold. The “best” VST cell line is rapidly identified and immediately released for delivery to the treatment center, where it can be thawed and infused to patients without the need for additional manipulation.

Our Highly Innovative Allogeneic VST Therapy Candidates

Our pipeline of allogeneic, off-the-shelf VST therapy candidates is designed to restore virus-specific T-cell immunity in patients suffering from, or at risk for, life-threatening viral diseases. Our proprietary VST therapy platform can be used to generate allogeneic cell therapies targeting single or multiple viruses at commercial scale. To date, we have observed promising preliminary disease outcome and safety data in 118 patients treated with our allogeneic off-the-shelf VSTs derived from third-party donors and we own worldwide development and commercialization rights to all of our cell therapies.



Viralym-M (ALVR105)

Our lead product candidate, Viralym-M, is a multi-VST therapy targeting five viral pathogens: BKV, CMV, AdV, EBV, and HHV-6, which has the potential to fundamentally transform the treatment landscape for immunocompromised individuals. Since the BKV target antigens used to create Viralym-M have a high level of sequence homology with those encoded by the JC virus, or JCV, this product candidate may also have the potential to target JCV.

We are initially focusing the development of Viralym-M in immunocompromised HSCT and SOT patients who are at high risk for life-threatening viral infections and are focused on the use of Viralym-M as follows:

- Treatment of Virus-Associated Hemorrhagic Cystitis (BKV, CMV and/or AdV)
- Treatment of CMV Infections
- Treatment of AdV Infections
- Prevention of Multi-Virus Infections (BKV, CMV, AdV, EBV, HHV-6 and JCV)
- Treatment of BKV Infections in Kidney Transplant Patients
- Treatment of CMV Infections in SOT Patients

Viralym-M is designed to restore virus-specific T-cell immunity and eradicate active viral infections and associated morbidities. We believe that Viralym-M has the potential to fundamentally transform the management of viral infections in HSCT and SOT patients, as well as in other individuals at high risk for opportunistic infections. We believe that Viralym-M will substantially reduce or prevent virus-associated morbidity and mortality and dramatically improve outcomes for patients with otherwise devastating viral diseases.

Based on the data generated from our Phase 2 proof-of-concept trial and the critical medical need, Viralym-M has been granted PRIME designation by the EMA for the treatment of serious infections caused by the five targeted viruses in HSCT patients. Moreover, Viralym-M was granted a RMAT designation by the FDA for the treatment of HC caused by BKV in adults and children following allogeneic HSCT. Viralym-M was one of only the first seven investigational therapies to receive both PRIME and RMAT designations. While these designations may not lead to a faster development process and do not increase the likelihood that a product candidate will receive approval from the FDA or EMA, we expect that PRIME and RMAT designation will result in increased EMA and FDA interactions to support our development efforts and may enable an expedited regulatory review process. In addition, the EMA's Committee for Orphan Medical Products granted orphan medicinal product designation to Viralym-M for all five targeted viruses in HSCT patients.

Viralym-M for Allogeneic HSCT Patients

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



Figure 7. Viralym-M is designed to treat and prevent viral diseases until the patient's own immune system recovers

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

Viralym-M Phase 2 Proof-of-concept CHARMS Clinical Results in Allo-HSCT Patients

We evaluated Viralym-M in a Phase 2 open-label proof-of-concept trial where VSTs were administered to 58 allogeneic HSCT patients with treatment-refractory infections. We refer to this trial as CHARMS.

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

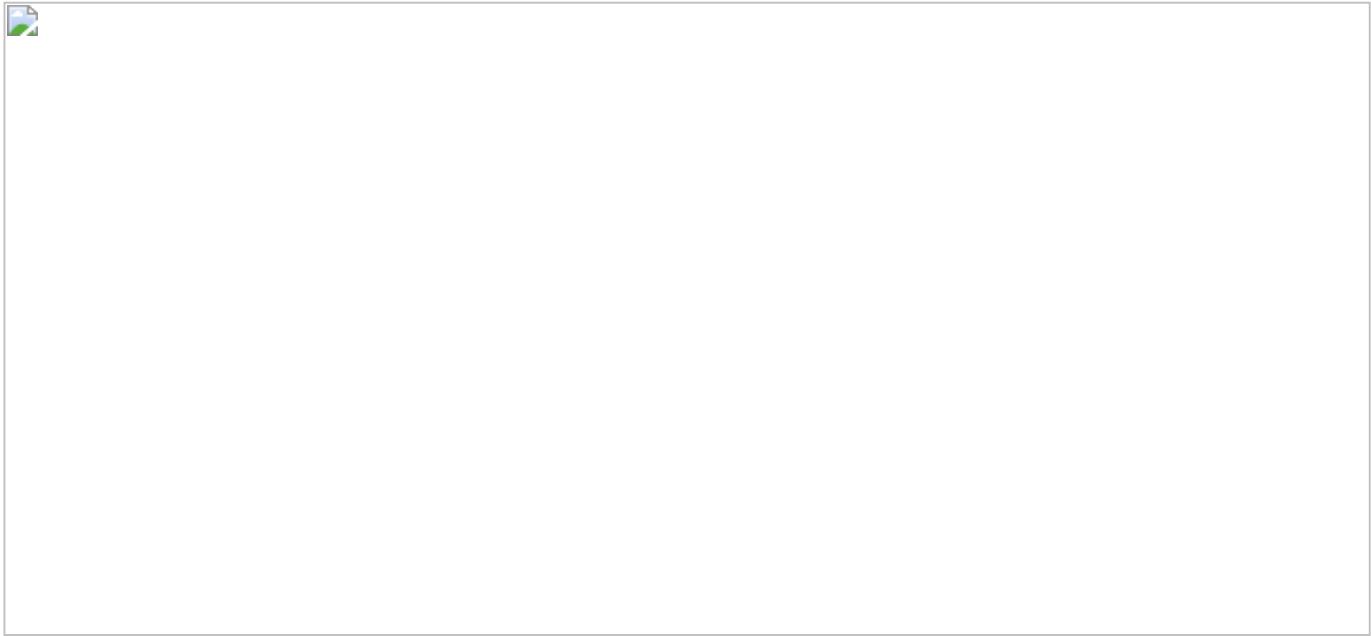


Figure 8. CHARMS—Phase 2, proof-of-concept, open label trial design

The treatment schedule encompassed an initial single infusion of 2×10^7 partially HLA-matched multi-VSTs/m². If the patients had a partial response, or a PR, within 28 days of the first infusion, as defined by a 50% or greater fall in viral load, they were eligible to receive up to four additional doses from day 28 after the initial infusion and at two weekly intervals from day 28.

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

The demographics and clinical characteristics for the 58 unique patients enrolled and treated in the CHARMS trial are presented in Table 1. These patients were infused with Viralym-M therapy matched at one to seven HLA alleles. In this clinical trial, we observed the delivery of partially HLA matched VSTs were generally well-tolerated. These interim trial results were published in the Journal of Clinical Oncology in August 2017.

Characteristic	Number (%)	
<i>Sex (N = 59)^a</i>		
Male	30 (50.8)	
Female	29 (49.2)	
<i>Age (N = 59)^a</i>		
Pediatric (≤ 18 years of age)	19 (32.2)	
Adult	40 (67.8)	
<i>Race (N = 59)^a</i>		
Black or African American	3 (5.1)	
White	53 (89.8)	
Asian	3 (5.1)	
<i># of patients with Viral infections (N = 59)^a</i>		
BKV	18 (30.5)	
CMV	17 (28.8)	
AdV	8 (13.6)	
HHV-6	3 (5.1)	
EBV	1 (1.7)	
JCV	1 (1.7)	
Multi-virus infections	BKV+CMV	3 (5.1)
	CMV+AdV	3 (5.1)
	BKV+AdV	1 (1.7)
	BKV+EBV	1 (1.7)
	BKV+HHV-6	1 (1.7)
	AdV+EBV	1 (1.7)
	BKV+CMV+AdV	1 (1.7)
<i>Number of infusions per patient (N = 59)^a</i>		
1	44 (74.6)	
2	11 (18.6)	
3	4 (6.8)	

^a The CHARMS trial treated 58 unique patients. One patient was counted twice: enrolled twice, treated first for AdV and then for JCV. One patient with HHV-6 was not evaluable for response rate.

Table 1. CHARMS clinical trial patient demographic and clinical characteristics.

Clinical and Virologic Response

Of the 58 unique patients evaluated for efficacy by 6 weeks post infusion, 17 had a CR and 37 had a PR, representing a 93% response rate, as depicted in the figure below. Of the 57 unique patients evaluated for efficacy by 12 weeks post infusion, 41 had a CR and 12 had a PR. NR was observed in four patients: two with AdV, and one each with CMV and HHV-6.

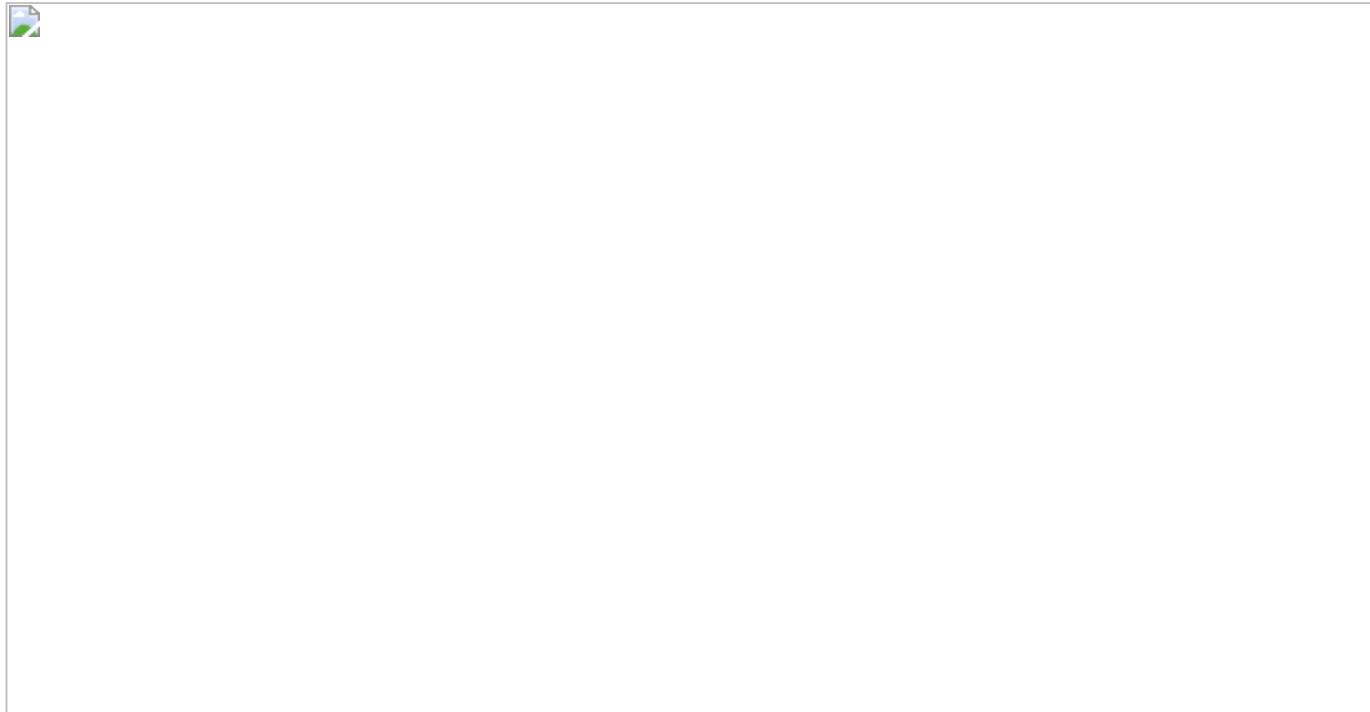


Figure 9. Viralym-M Phase 2 proof-of-concept trial (CHARMS): 93% overall response rate in patients with viral disease by 6 weeks in 58 unique patients

Eleven patients with 23 drug refractory viral infections were treated with Viralym-M. Ten patients were co-infected with 2 different viruses and 1 patient had infections with 3 different viruses. All 11 patients (19 of 23 viral infections) responded to Viralym-M by 6 weeks post-infusion. This demonstrates the potential for treating patients with multiple viral infections with off-the-shelf Viralym-M.

In Vivo VST Persistence

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

Safety Profile

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

Safety monitoring in the CHARMS trial consisted of several assessments, including assessments of both GVHD and serious adverse events, or SAEs, as reflected in the table below. Overall, 23 deaths, including six grade 5 SAEs, occurred during the trial; none of these deaths were deemed to be treatment-related. Seven grade 4 SAEs were reported from seven patients, five of whom also had grade 5 SAEs. Like the grade 5 SAEs, grade 4 SAEs or *de novo* GVHD were not deemed to be treatment-related. In general, safety findings were consistent with those expected in an allogeneic HSCT patient population, including the known risks of GVHD. To date, no overt safety signal has been detected above and beyond the safety findings expected to be found in patients who have already undergone allogeneic HSCT.

14 patients with acute GVHD (through 42 days post last infusion)	<p><u>8 patients with pre-existing GVHD</u></p> <ul style="list-style-type: none"> • 3 grade I and 1 grade II skin GVHD: resolved or improved with topical treatment • 2 grade I skin GVHD: unchanged with topical treatment and/or low-dose corticosteroid • 1 grade II skin GVHD flare: resolved after prednisone dose was restored to pre-infusion level • 1 grade III GI GVHD flare: occurred coincident with rapid corticosteroid taper, resolved upon increased cortisone dose <p><u>6 patients with <i>de novo</i> GVHD</u></p> <ul style="list-style-type: none"> • 4 grade I skin GVHD: resolved with topical treatment • 1 grade I skin GVHD: resolved with tacrolimus and prednisone • 1 grade I skin GVHD: resolved with topical treatments plus IV hydrocortisone
6 grade 5 SAEs (deaths)	<ul style="list-style-type: none"> • 3 multi-organ failure • 1 respiratory failure • 1 death with progressive disease • 1 death not otherwise specified
7 grade 4 SAEs (reported from 7 patients, 5 of whom also had Grade 5 SAEs reported and are included above)	<ul style="list-style-type: none"> • 2 respiratory failure • 2 aspartate aminotransferase increased • 1 hypoxia and dyspnea • 1 sepsis • 1 vomiting

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

Treatment of Virus-Associated Hemorrhagic Cystitis

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

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

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

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

- 22% of patients developed grade 2 or higher HC, and 18% had a high level of BK viremia ($\geq 10,000$ copies/mL) in the first three months post-HSCT;
- Patients with a high level of BK viremia in the first three months after transplant had a significantly lower estimated glomerular filtration rate, or eGFR, at 12 and 24 months (on average 20mL/min/m² lower by two years after transplant) and a 6-fold higher risk of receiving dialysis ($p=0.004$);
- Patients with high levels of BK viremia have been found to have significant reduction in kidney function (17-26% below baseline) as compared to patients with low levels of BK viremia (4-5% below baseline). Additionally, 18% of patients with high levels of BK viremia required dialysis, compared to 3% of patients with low levels of BK viremia;

- A high level of BK viremia was associated with a significantly higher risk of death;
- Virus-associated HC has been associated with increased mortality, with patients with high levels of BK viremia experiencing mortality rates of 44%, compared to 19% in patients with low levels of BK viremia;
- Asymptomatic viremia was common and associated with decreased kidney function, and;
- Patients with detectable BKV-specific T-cells were 5-fold more likely to clear viremia, but patients who received off-label cidofovir were not.

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

Viralym-M Clinical Data—BKV

In our Phase 2 proof-of-concept trial for Viralym-M, we treated 25 evaluable patients with BKV disease. Of those, 18 patients were infected with BKV alone and all 18 patients responded to Viralym-M therapy. Seven patients had BKV and were co-infected with at least one other virus: three with CMV, one with AdV, one with EBV, one with HHV-6 and one with both CMV and AdV, and all seven patients responded to therapy. This resulted in a 100% overall response rate for BKV across 25 patients. Overall response rates were defined as achieving either a PR or CR by six weeks post-infusion, as described in the protocol criteria.

In 20 patients infused with Viralym-M, HC severity was retrospectively graded using the National Cancer Institute cystitis grading scale. This was performed by three physicians independently based on chart review of clinical and laboratory documentation. As documented in the figure below, patients treated with Viralym-M therapy showed a rapid improvement in disease severity as assessed at weeks 2, 4 and 6.

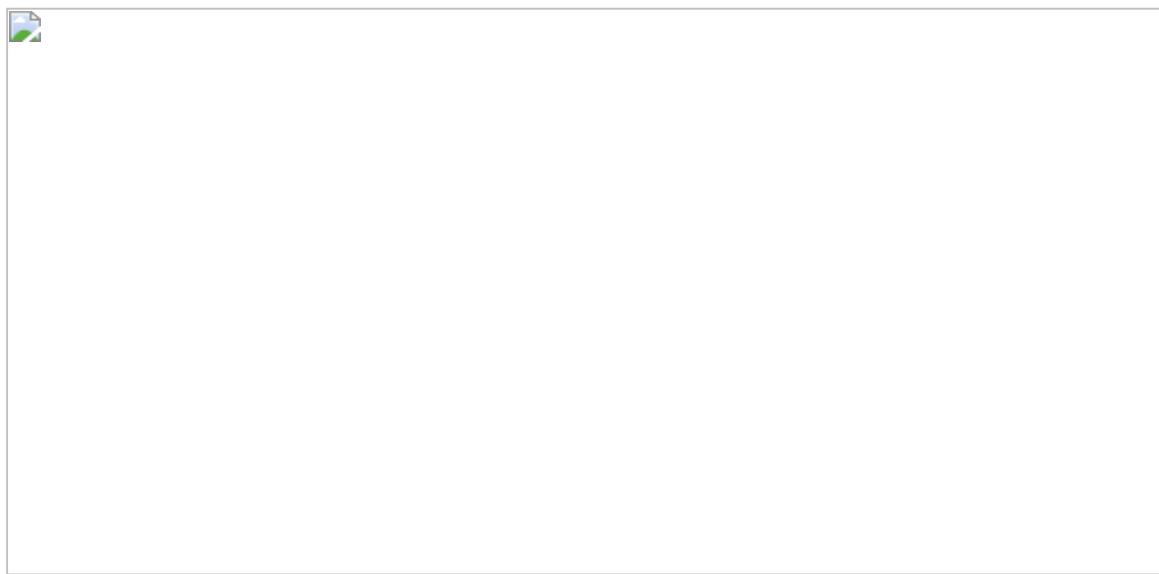


Figure 10. Rapid Grade Reduction of BKV HC following treatment with Viralym-M therapy.

Approximately 60% of the CHARMS cohort's patients had resolved their disease within two weeks of infusion. By week 6, the percentage of patients with resolved disease increased to approximately 75% as depicted in the figure below.

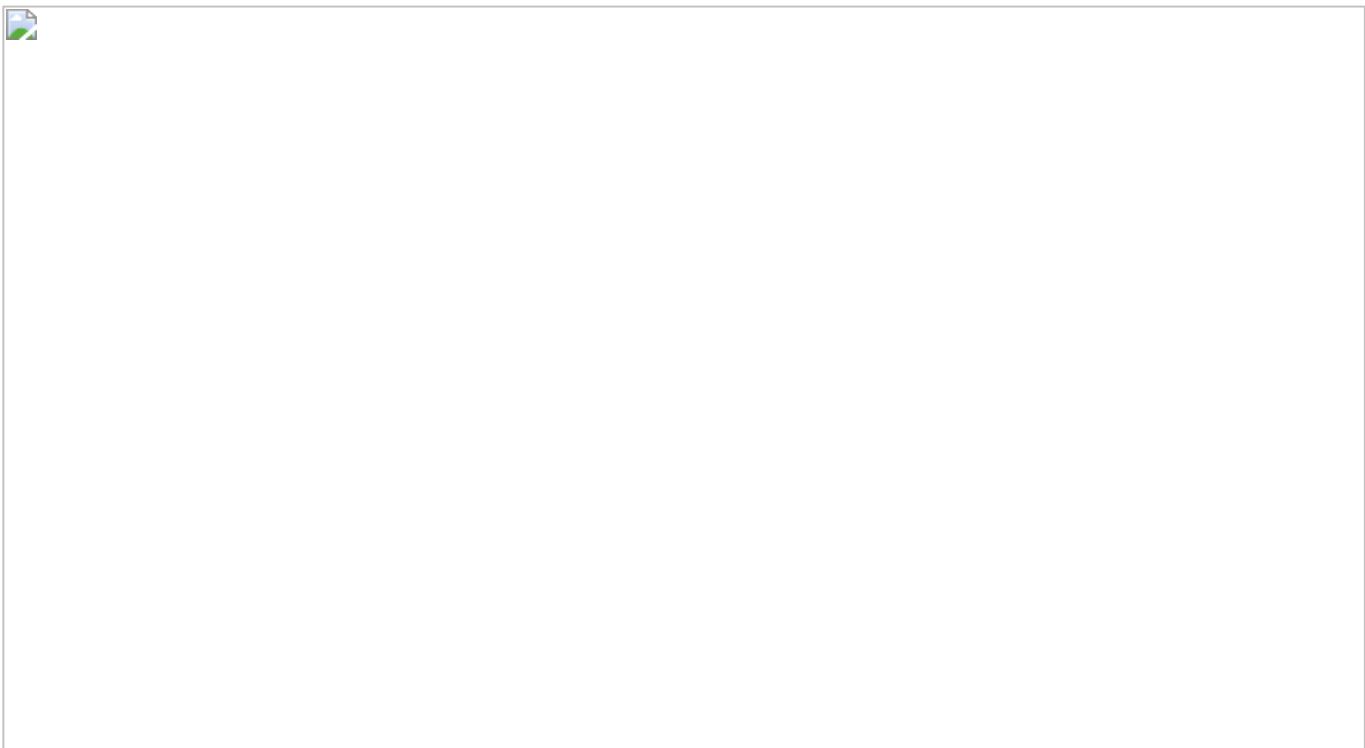
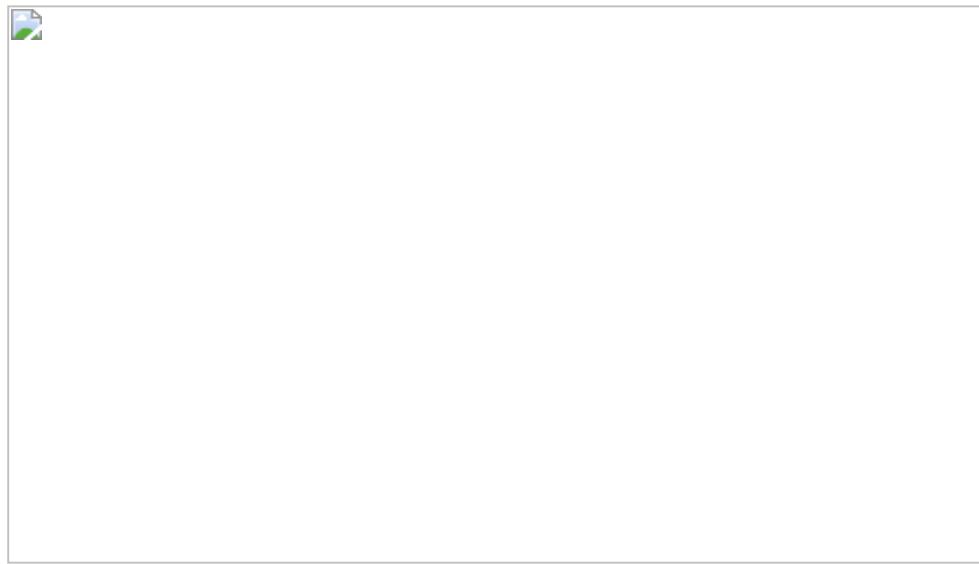


Figure 11. Time to resolution of BKV-HC following treatment with Viralym-M therapy

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



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

Clinical Development Plan

We have initiated our Phase 3 virus-associated-HC registrational trial. This Phase 3, multicenter, randomized, double-blind, placebo-controlled trial is designed to assess the safety and efficacy of Viralym-M therapy compared to placebo for the treatment of patients with virus-associated HC following allogeneic HSCT. The primary endpoint will be the time to resolution of macroscopic hematuria. As these HSCT patients often experience multiple viral infections, we plan to examine secondary endpoints for the ability of Viralym-M to reduce or eliminate viral loads for CMV, AdV, EBV, HHV-6 and JCV.

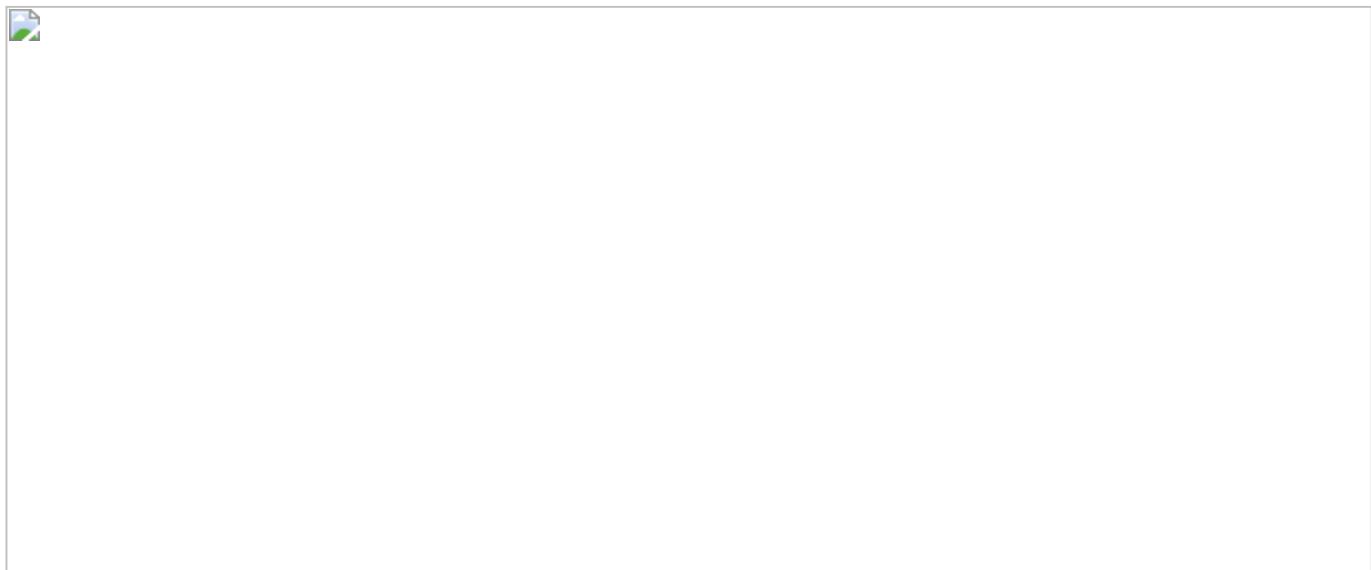


Figure 12. Phase 3, multicenter, randomized, double-blind, placebo-controlled virus-associated HC trial design

In addition to the PRIME and orphan drug designations granted by the EMA, Viralym-M has received an RMAT designation from the FDA for the treatment of HC caused by BKV in adults and children following an allogeneic HSCT. We expect that RMAT designation will result in increased FDA interactions to support our development efforts and may enable an expedited regulatory review process for product approval.

Treatment of Cytomegalovirus Infections

Cytomegalovirus is a herpesvirus that establishes life-long latency after primary infection. Cellular immunity driven by T-cells is responsible for controlling CMV replication. However, immunocompromised patients such as HSCT patients are vulnerable to CMV recurrence, leading to symptomatic CMV infections and end-organ disease. CMV, which affects 65% of allogeneic HSCT patients, is the most common virus detected.

In most cases, CMV recurrence occurs between two and four months after HSCT, with a median onset time of 44 days. The median time to development of overt CMV tissue invasive disease is 104 days, with a range of 39–200 days.

The most frequent clinical manifestations of CMV disease in immunocompromised patients are pneumonia, hepatitis, bone marrow suppression, enteritis and retinitis. Pneumonia is the most serious manifestation of CMV in HSCT patients and has a mortality rate of more than 50%. CMV can also affect the entire GI tract, causing severe inflammation and ulceration extending deep into the submucosal layers, putting the patient at risk for perforation. Retinitis may also occur with CMV disease, presented initially with decreased visual acuity and blurred vision, involving both eyes in 60% of patients. If untreated, the risk of vision loss is high. Other manifestations include hepatitis and encephalitis. CMV reactivation can cause immunosuppression or graft failure that may result in the development of concurrent infectious complications.

There are no FDA- or EMA-approved anti-viral agents for the treatment of CMV infection and disease other than CMV retinitis. Off-label use of ganciclovir, valganciclovir and foscarnet has been associated with severe toxicities, including myelosuppression and nephrotoxicity, that limit their use in the HSCT population.

Viralym-M Clinical Data-CMV

In our CHARMS trial, of 24 patients with CMV infections, 17 patients were infected with CMV alone and seven patients (of whom five had response data) were co-infected with another virus: three with AdV, three with BKV and one with BKV and AdV. The overall response rate to CMV by six weeks post-infusion was 94% for patients infected with CMV alone and 71% (5/7) for patients infected with additional viruses.

Clinical Development Plan

We anticipate initiating our Phase 3 CMV trial in 2021. The trial is expected to be multicenter, randomized, double-blind, placebo-controlled trial designed to assess the safety and efficacy of Viralym-M therapy for the treatment of allogeneic HSCT patients with CMV infections.

Treatment of Adenovirus Infections

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

Viralym-M Clinical Data—AdV

In our CHARMS trial, of 14 patients with AdV infections, eight patients were infected with AdV alone and six (of whom 4 had response data) were co-infected with at least one other virus: three with CMV, one with BKV, one with EBV and one with BKV and CMV. The overall response rate to AdV by six weeks post-infusion was 75% (6/8) for AdV alone and 67% (4/6) for patients infected with additional viruses.

Clinical Development Plan

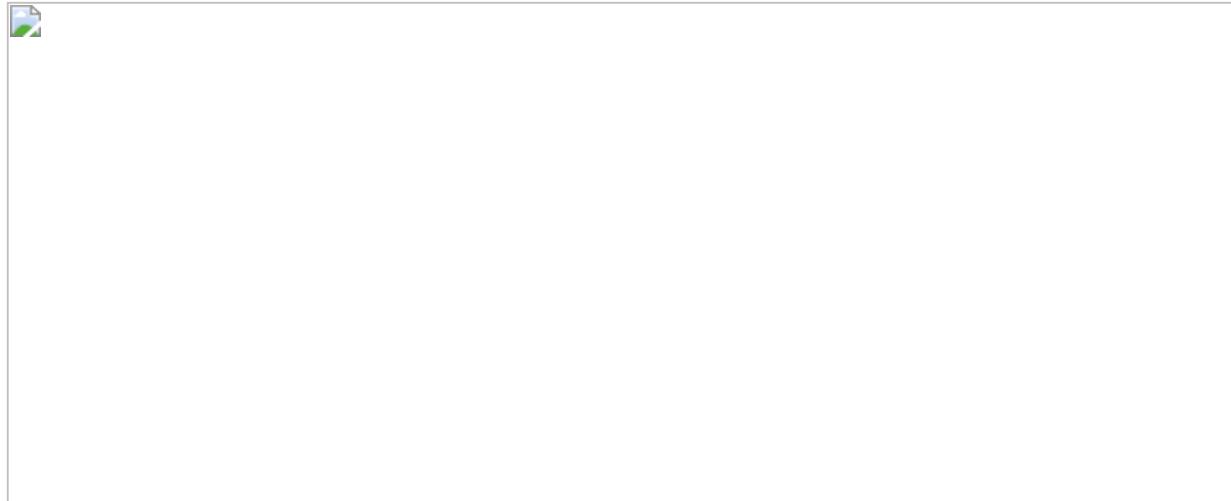
We anticipate initiating our Phase 3 AdV trial in 2021. The Phase 3 trial is expected to be multicenter, randomized, double-blind, placebo-controlled trial designed to assess the safety and efficacy of Viralym-M therapy for the treatment of allogeneic HSCT patients with AdV infection.

Prevention of Multi-Virus Infection and Associated Disease

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

Clinical Development Plan

We have initiated our Phase 2, proof-of-concept trial with Viralym-M for the prevention of clinically significant viral infection and disease in allogeneic HSCT patients and expect initial data from an open label cohort in the second half of 2021. In this trial we are evaluating Viralym-M both as a prophylactic therapy in high-risk patients in patients who have no evidence infection or disease by any of the target viruses and as a preemptive therapy in patients who have already reactivated one or more of the targeted viruses. The trial has both an open label phase with data to report out later this year as well as a multicenter, randomized, double-blind, and placebo-controlled with data expected in 2022. This trial is designed to assess both the safety and efficacy of Viralym-M for the prevention of multiple viral infections and/or diseases in allogeneic HSCT patients.

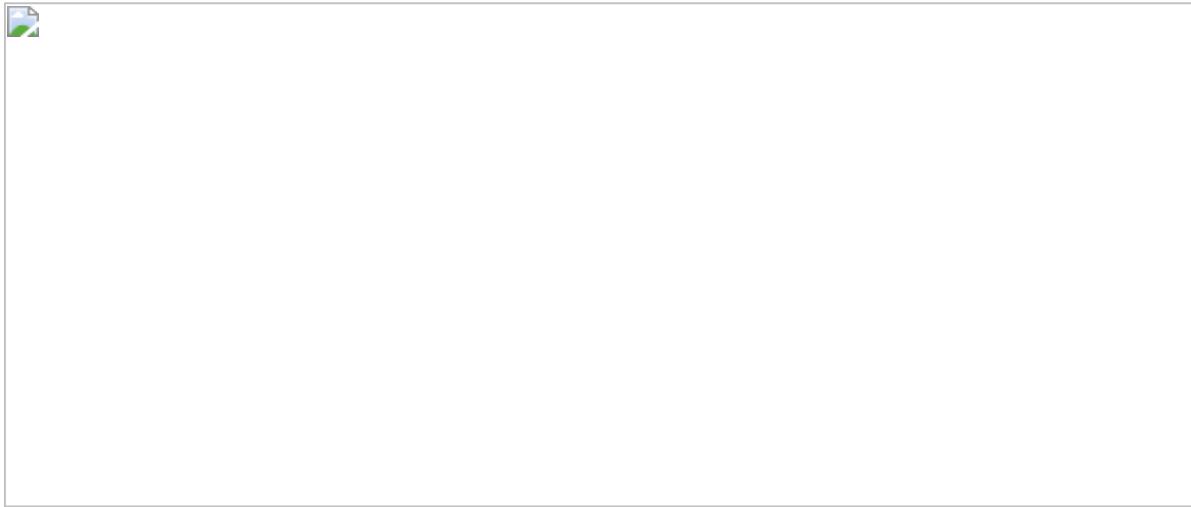


Treatment of BKV Infections in Kidney Transplant Patients

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

Clinical Development Plan

We have initiated a proof-of-concept trial with Viralym-M for the treatment of BKV in KT patients, with interim data expected in 2021. This Phase 2 multicenter, randomized, double-blind, placebo-controlled trial is designed to assess the safety, tolerability and effectiveness of adoptively transferred Viralym-M in KT patients with BK viremia.



Treatment of Cytomegalovirus Infections in Solid Organ Transplant Patients

Cytomegalovirus is a significant cause of morbidity, mortality and graft loss in SOT patients. CMV infection or disease is the most common viral complication after SOT with 25-40% of patients developing symptomatic disease.

Clinical Development Plan

We anticipate initiating a proof-of-concept trial with Viralym-M for CMV infections in SOT patients in the second half of 2021.

Other Viruses Targeted by Viralym-M

Epstein Barr Virus

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

PTLD can occur at any age and after all types of transplant, though allogeneic HSCT patients are at particular risk. The median time to development of EBV-associated PTLD, or EBV-PTLD, after HSCT is two to four months. Fever and lymphadenopathy are the most common symptoms and signs of EBV-PTLD and, if not treated, PTLD generally progresses rapidly to multi-organ failure and death. Off-label rituximab has been used to treat EBV-PTLD. However, response to rituximab is not universal and mortality remains high in rituximab-refractory patients.

In our CHARMS trial, three evaluable patients with EBV infections were treated with Viralym-M, one patient was infected with EBV alone and two were co-infected with at least one other virus: one with AdV and one with BKV. The overall response rate to EBV by six weeks post-infusion was 100% for EBV alone and EBV co-infected with another virus.

Human Herpesvirus Type 6

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

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

In our CHARMS trial, three evaluable patients with HHV-6 infections were treated with Viralym-M. One additional treated patient was not evaluable. Two of the evaluable patients were infected with HHV-6 alone and one was co-infected with BKV. The overall response rate by six weeks post-infusion was 50% (1/2) for HHV-6 alone and 100% (1/1) for HHV-6 co-infected with BKV.

Viralym-M Commercial Opportunity

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 focused on the global development and commercialization of Viralym-M as we see a large opportunity to serve patients suffering from devastating viral diseases and infections worldwide.

For our initial launch indications for the treatment and prevention of viral diseases in transplant patients, we believe approximately 30% of our annual addressable patient population is in the United States, 35% in the European Union, 5% in Japan, and 30% in eleven other target markets in the rest of the world. There were 144,000 HSCT and SOT procedures performed in 2018 in our target markets in North America, Europe, and select markets in Asia Pacific and Latin America. Based on established epidemiology of our initial target indications, we believe this represented approximately 81,000 transplant patients annually that could have benefited from an allogeneic off-the-shelf VST therapy like Viralym-M. As shown in the figure below, we project the addressable transplant patient population for Viralym-M for the treatment and prevention of our target viral diseases will increase to approximately 97,000 HSCT and SOT patients annually in 2025 based on conservative 2-3% annual growth observed for HSCT and SOT procedures. There is significant unmet demand for HCST procedures as a result of the lack of access to matched or unmatched stem cell donors. By treating and preventing viral diseases, we believe that Viralym-M can address this unmet medical need by enabling more patients to benefit from a curative haploidentical HSCT procedure, which represents the fastest growing subset of the existing allogeneic HSCTs.

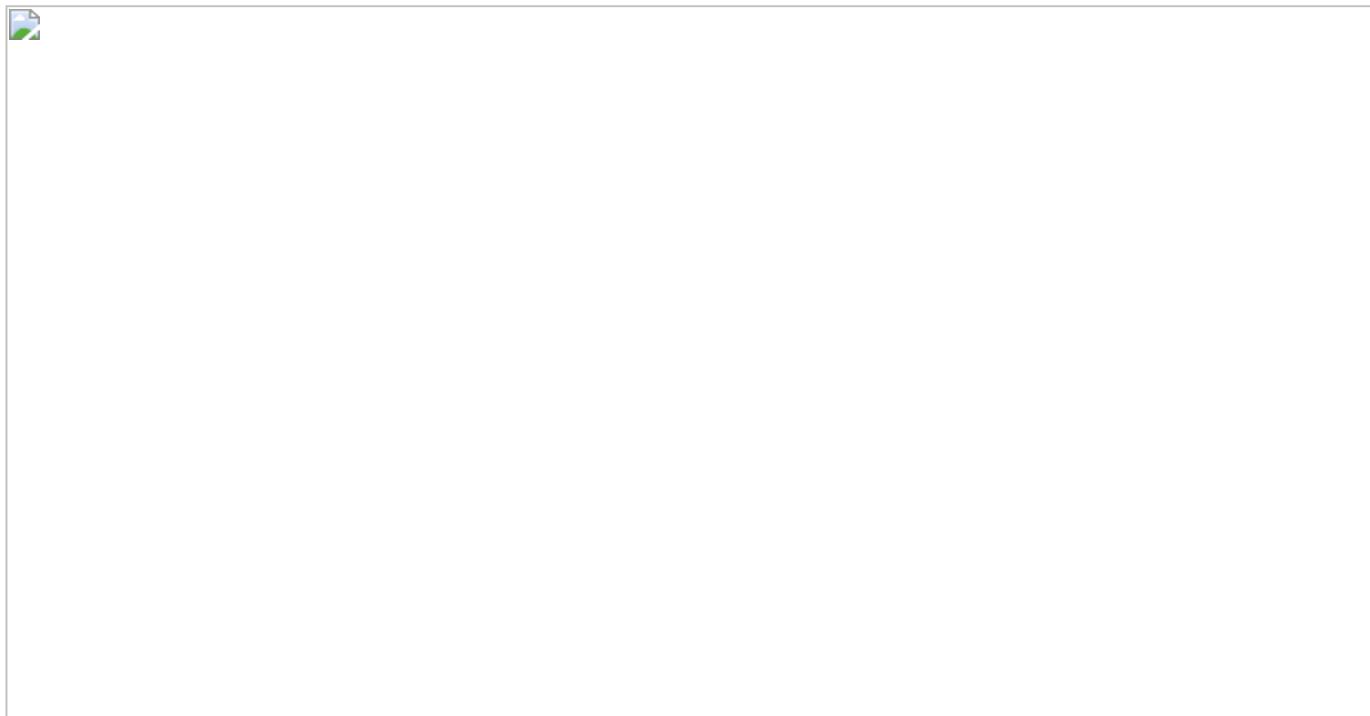


Figure 13. Viralym-M has a large market opportunity to treat and prevent devastating viral diseases

1—Viralym-M Treatment in Allogeneic HSCT Patients

We estimated that in 2018 approximately 36,000 allogeneic HSCTs were performed in our target markets. We project this to grow by 3% annually to approximately 44,000 procedures per year by 2025 and estimate that approximately 19,500 allogeneic HSCT patients will be eligible for Viralym-M therapy for virus-associated HC, AdV and CMV.

The observed incidence of virus-associated HC is 8-25% and 7-54% in pediatric and adult patients, respectively, and is higher after allogeneic HSCT than after autologous HSCT, particularly after haploidentical HSCT with post-transplant exposure to cyclophosphamide as prophylaxis for GVHD. By 2025, we estimate there will be 6,500 allogeneic HSCT patients annually who develop virus-associated HC.

The incidence of AdV viremia is 32% among pediatric allogeneic HSCT patients and 6% among adult allogeneic HSCT patients. By 2025, we estimate there will be 5,000 allogeneic HSCT patients annually who develop AdV viremia.

CMV is the most common virus in allogeneic HSCT patients affecting 65% of patients. Despite the approval of letermovir as a prophylactic agent, 18% of treated patients still experienced clinically significant CMV infections. We estimate by 2025 there will be approximately 8,000 allogeneic HSCT patients annually with clinically significant CMV infections despite treatment with letermovir.

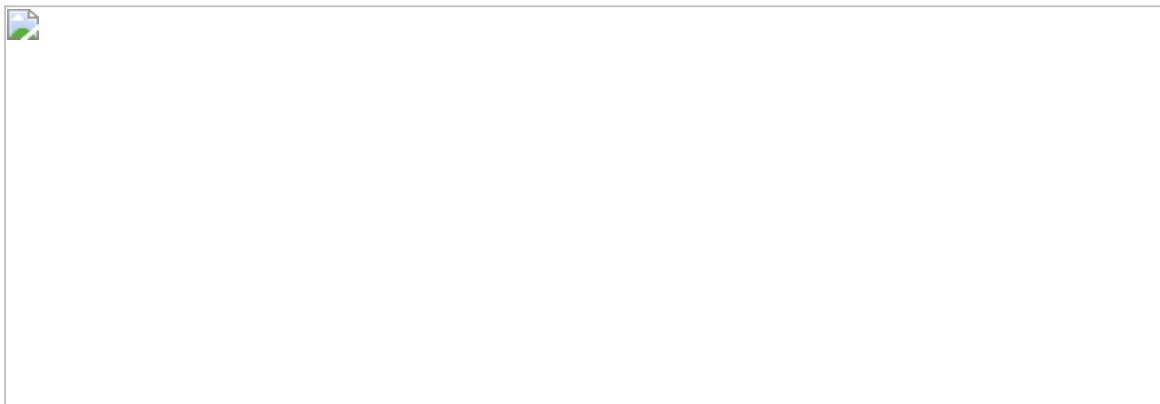


Table 3. Addressable population of potential patients for Viralym-M for the three lead indications in the treatment of HSCT

An analysis from the National Marrow Donor Program calculated that the demand for HSCT procedures exceeded the number performed in the United States by approximately 290%. Lack of access to HLA matched or unmatched stem cell donors is a contributing factor to the unmet demand for allogeneic HSCT. To broaden the pool of donors designed to assess the safety and efficacy of Viralym-M therapy for the treatment of allogeneic HSCT patients with CMV infections, researchers developed haploidentical transplants, in which a healthy first degree relative can often serve as a donor. Instead of a near-total HLA match, donors for a haploidentical transplant need to be only a 50% match to the patient. In addition to making it easier to find a suitable donor, haploidentical transplants can often be performed more promptly than traditional unrelated donor transplants. Importantly, this enables more patients to receive this curative treatment option for their underlying diseases faster. The successful outcome of haploidentical HSCT is dependent on the use of T-cell-replete conditioning strategies, which in turn leaves patients highly vulnerable to viral diseases and infections. By treating and preventing viral diseases and infections, we believe that Viralym-M can accelerate the paradigm shift toward haploidentical HSCT and enable more patients to benefit from this curative HSCT procedure.

2—Viralym-M Multi-Virus Prevention in HSCT Patients

We are developing Viralym-M for the prevention of clinically significant viral diseases and infections in allogeneic HSCT patients, either as a prophylactic therapy in high-risk patients or as a preemptive therapy in patients who reactivate one or more of the viruses targeted by Viralym-M. As 90% of allogeneic HSCT patients reactivate at least one virus targeted by Viralym-M, we estimate that the addressable patient population for the multi-virus prevention indication will be 40,000 allogeneic HSCT patients in 2025. We believe that Viralym-M, if approved, has the potential to redefine the treatment landscape for viral diseases.

3—Viralym-M Treatment for Solid Organ Transplant Patients

We are developing Viralym-M for the treatment of BK viremia in KT patients and clinically significant CMV infections in SOT patients. We estimate that approximately 108,000 SOTs were performed in 2018 in our target markets, of which 67,000 were KTs. We project this to grow by 2% annually to 124,000 SOTs by 2025, of which 77,000 are for kidney transplant, and estimate that approximately 57,000 KT and SOT patients will be eligible for Viralym-M therapy for BK viremia and CMV.

BK viremia is detected in up to 20% of KT patients and up to 50% of patients with BK viremia will progress to BK nephropathy, resulting in decreased graft function and graft survival. We estimate that there will be over 14,000 KT patients annually who will develop BK viremia and can benefit from Viralym-M therapy.

Despite prophylactic or pre-emptive therapy with available antivirals, CMV infection and disease is the most common viral complication after SOT with 25-40% developing symptomatic disease after cessation of prophylaxis. We estimate that in 2025 there will be over 43,000 SOT patients annually in our target markets with clinically significant CMV infections.

4—Viralym-M for Other Viruses Associated with Transplant and Immunocompromised Patients

We believe Viralym-M can also address high unmet medical need in transplant patients with viral diseases associated with EBV, HHV-6, and JC viruses. EBV-PTLD is a severe complication after allogeneic HSCT. PTLD was diagnosed in 4% of HSCT patients. There are currently no FDA- or EMA-approved therapies globally for patients with EBV-PTLD. Over 90% of individuals are infected with HHV-6 before the age of two. In over half of allogeneic HSCT patients, HHV-6 is reactivated resulting in clinical manifestations such as encephalitis, delayed engraftment and an increased rate of GVHD leading to increased mortality. Up to 80% of the general population is seropositive for JCV. Rates of PML, the primary disease caused by JC virus, are elevated in HSCT patients. The median survival time for HSCT patients with PML is less than two years.

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

Our Commercialization Plan

If approved, we intend to commercialize our highly innovative off-the-shelf VST therapies globally to serve a large number of patients suffering from the life-threatening consequences of viral diseases. Initially, to launch our late clinical stage therapies for the treatment of transplant patients, we will establish a focused commercial infrastructure targeting high-volume transplant centers globally. Based on the relatively small number of transplant centers that perform the majority of these transplant procedures, we believe that the entire target market for our VST therapies could be served by a small global team. In the US, there are 185 stem cell transplant centers, of which the top 70 centers perform 80% of the allogeneic HSCT, and in the five major European countries (Germany, France, UK, Italy, Spain) there are 411 stem cell transplant centers, of which the top 129 centers perform 80% of allogeneic HSCT. Furthermore, in the US there are 240 centers performing kidney transplants, of which the top 100 centers perform 80% of the transplants. We believe that many of these same transplant centers will also have participated in our pivotal and proof-of-concept trials for Viralym-M and ALVR106 and will have significant experience with our investigational VSTs, which will support commercial launch and adoption of our therapies. As we eventually progress to serve non-transplant patients at high-risk for the life-threatening consequences of viral diseases, we will expand our global commercial capabilities.

Our team has extensive experience launching and commercializing specialty pharmaceuticals globally with a strong track record of achieving broad patient access resulting in industry leading product launches. By targeting severe viral diseases that result in prolonged hospitalization, multi-organ disease and failure and increased risk of death, and currently have limited or no treatment options, we believe that our therapies have the potential to transform the lives and care of patients globally.

Transplant-Related Viral Diseases Cause Significant Burden to the Healthcare System

Along with increased morbidity and mortality, viral diseases and infections in allogeneic HSCT patients have a significant impact on healthcare costs. We conducted a real-world claims analysis to assess the economic burden, health resource utilization, and clinical outcomes between allogeneic HSCT patients with virus-associated hemorrhagic cystitis and those without virus-associated HC. The study population included 13,363 patients with a first (index) allogeneic HSCT procedure between January 1, 2012 and December 31, 2017 from the Decision Resources Group Real World Evidence Data Repository. As shown in the figure below, HSCT patients with virus-associated HC had significantly higher mortality ($p=0.0048$) and incur greater healthcare reimbursement costs ($p<0.0001$) in the 1-year post allogeneic HSCT. After adjusting for baseline characteristics, presence of GVHD during follow-up, follow-up duration and number of comorbidities, mean reimbursement costs were \$195,200 higher for allogeneic HSCT patients with virus-associated HC versus allogeneic HSCT patients without virus-associated HC (\$539,300 versus \$344,100; $p<0.0001$). Patients with virus-associated HC had higher length of stay (LOS) for the index hospitalization ($p<0.0001$), higher readmission rate ($p<0.0001$) and higher number of days in the hospital after the index hospitalization ($p<0.0001$).

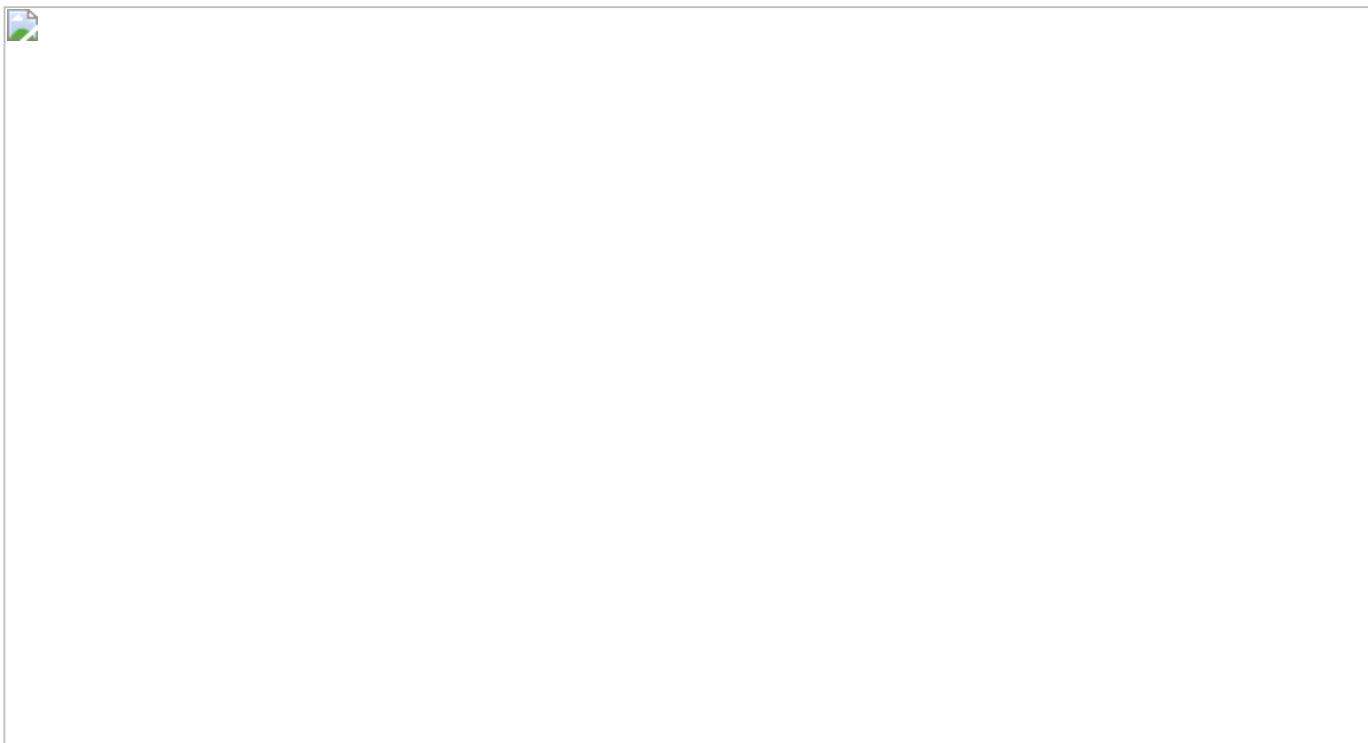


Figure 14. Real-world claims analysis confirms high clinical and economic burden of virus-associated HC.

Separately, this claims analysis also showed that allogeneic HSCT patients with an increasing number of double-stranded DNA viral infections (BKV, CMV, AdV, EBV and HHV-6) have a significantly higher burden of reimbursements and healthcare resource utilization and poorer patient outcomes within one year of undergoing allogeneic HSCT. Adjusted mean reimbursement costs were \$269,000 for patients with no viral infection, \$392,900 for patients with one viral infection, \$522,800 for two viral infections, and \$743,300 for three or more viral infections. Our results are consistent with those previously published on the high economic burden of transplant-related viral infections.

ALVR106 and ALVR109 VST Therapy for Respiratory Viruses

Acute respiratory tract infections due to respiratory viruses including RSV, influenza, PIV, hMPV and coronaviruses such as SARS-CoV-2, the virus that causes COVID-19, are a major public health problem. For example, as of January 31, 2021, there were over 103.2 million confirmed SARS-CoV-2 cases and over 2.2 million directly attributable deaths worldwide, while RSV-induced bronchiolitis is the most common reason for hospital admission in children less than one year of age. The lack of approved antiviral agents to treat many respiratory viruses underscores the need for alternative treatment and prevention strategies.

We are developing two VST therapy candidates to target devastating respiratory viruses: ALVR106, an allogeneic off-the-shelf multi-virus-specific T-cell therapy for RSV, influenza, PIV, and hMPV, and ALVR109, an allogeneic, off-the-shelf VST therapy for SARS-CoV-2 and that we are developing in response to the ongoing global COVID-19 pandemic. We also amended our existing sponsored research agreement with BCM, which we refer to as the BCM SRA, to enable BCM to support their work on the initial discovery and development of allogeneic, off-the-shelf, virus specific T-cell therapies to combat SARS-CoV-2.

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

We are developing ALVR106 as an allogeneic, off-the-shelf VST therapy designed to treat or prevent four common respiratory viruses, RSV, influenza, PIV, and hMPV. ALVR106 is anticipated to enter Phase 1/2 clinical development in 2021 to target severe respiratory diseases in high-risk populations.



Figure 15: Consequences to high-risk patients with respiratory virus infections

Pre-Clinical Data

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

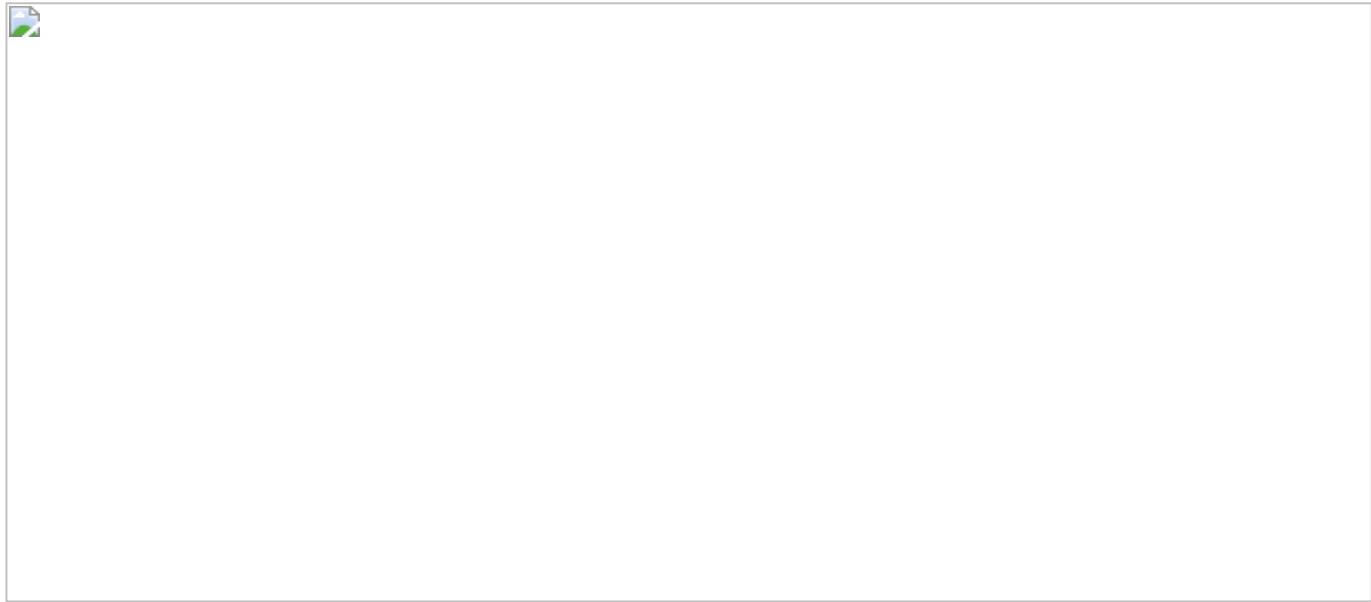


Figure 16. ALVR106 cells are reactive against virus-infected targets. (A) Cytolytic potential of ALVR106. Results are presented as percentage of specific lysis (mean±SEM). (B) Demonstration that multi-R-VST show minimal/no activity against either non-infected autologous or allogeneic PHA blasts.

Respiratory Virus Infections in HSCT Patients

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

RSV

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

Influenza

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

PIV

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

hMPV

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

Clinical Development Plan

We received clearance on our IND with the FDA for ALVR106 in the fourth quarter of 2020, covering infections and diseases caused by influenza, PIV, RSV and hMPV, and we anticipate initiating our Phase 1/2 clinical trial in autologous and allogeneic HSCT patients with respiratory viral diseases in the 2021-2022 respiratory virus season. This proof-of-concept trial is expected to be a Phase 1/2, double-blind, placebo-controlled, dose escalation and expansion trial of ALVR106 in addition to standard of care to assess safety and efficacy of ALVR106.

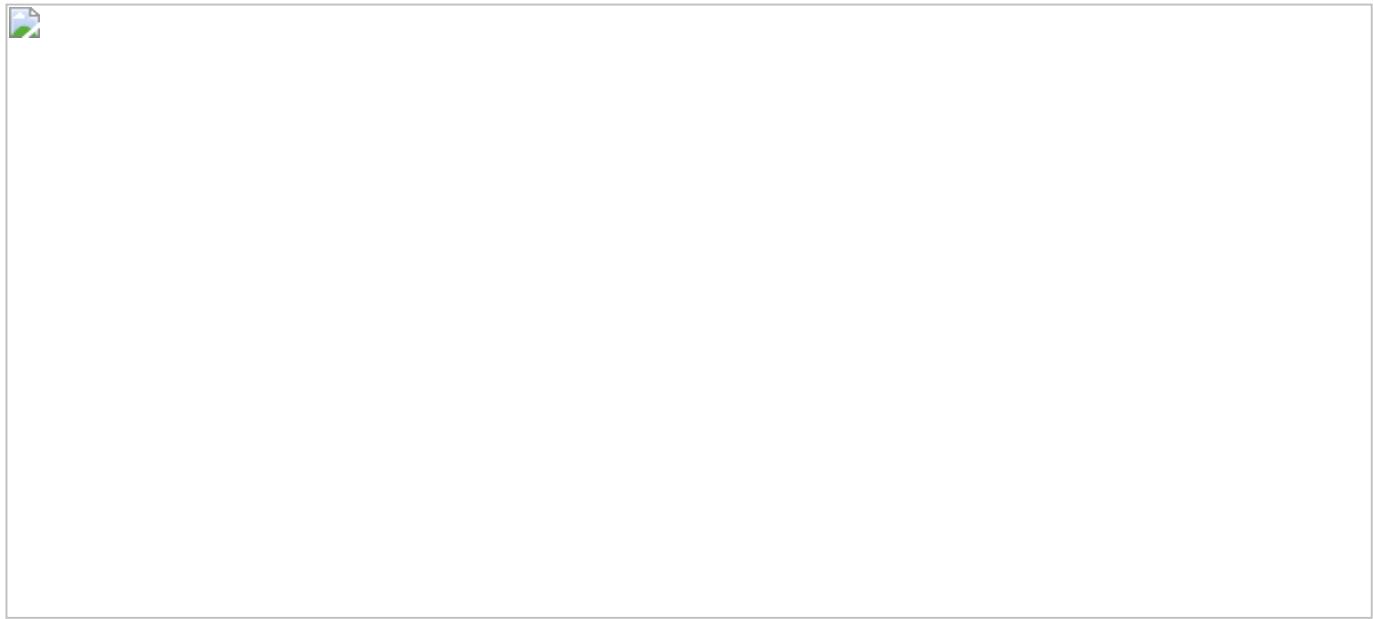


Figure 17. Proposed AVLR106 Phase 1/2 Proof-of-concept basket trial design

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

RSV

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

Influenza

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

PIV

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

hMPV

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

Clinical Development Plan

We also plan to test ALVR106 in high-risk patient populations outside of the transplant setting.

Commercial Opportunity

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

ALVR106 for Transplant Patients

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

We project the number of allogeneic and autologous HSCT procedures to grow 2-3% annually to approximately 44,000 and 59,000 procedures annually, respectively, by 2025 in our target markets in North America, Europe, Asia Pacific and Latin America. By 2025, we estimate there will be over 17,000 HSCT patients annually infected with one of the four respiratory viruses targeted by ALVR106. We believe that ALVR106 will be effective for treating infections in HSCT patients with one or more of the targeted respiratory viruses.

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

We project the number of new lung transplants to grow 2% annually to approximately 6,800 new lung transplants annually by 2025 in our target markets. We estimate the size of the prevalent lung transplant population to be over 56,000 patients in our target markets. By 2025, we estimate that there are annually over 12,000 lung transplant patients that are infected with one of the four respiratory viruses targeted by ALVR106.

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

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

ALVR109: VST Therapy for the Treatment of Patients with COVID-19

COVID-19

SARS-CoV-2 infection causes the severe and life-threatening viral disease, COVID-19. COVID-19 has become synonymous with profound depletion of endogenous T-cells, or lymphopenia, resulting in a state of acute immune deficiency, rendering infected individuals susceptible to developing overwhelming and sometimes fatal pneumonia. Beyond the lungs, COVID-19 is a multi-organ disease that affects the heart, kidneys, brain, liver and gastrointestinal tract, as well as causing blood clots.

Studies to date estimate that the risk of mortality is up to 500% higher in patients 65 years of age or greater than in those aged 30 to 59 years. In addition, other risk factors for severe COVID-19 include chronic lung or heart disease, hypertension, diabetes and underlying immune compromise. Accordingly, there is an urgent need to rapidly develop an effective therapy for COVID-19.

T-cells are known to play a critical role in controlling viral infections, including respiratory infections caused by SARS-CoV, the coronavirus with the highest known homology to SARS-CoV-2. Over 80% of hospitalized patients with COVID-19 are lymphopenic, with reduced CD8+ and CD4+ T-cell counts. These reductions in T-cell counts correlate negatively with survival. Reduced T-cell counts have been observed to be prevalent in older COVID-19 patients and those with severe illness, regardless of age. As further data on the immunogenicity of SARS-CoV-2 continues to emerge, the important protective role of SARS-CoV-2-specific T-cells is increasingly being recognized.

Current clinical management of COVID-19 relies almost entirely on supportive care measures. There are a number of investigational approaches in development, including preventative vaccines, antibody-based therapies and antivirals. ALVR109 is being developed as an allogeneic, off-the-shelf VST therapy candidate to arrest the progression of COVID-19 by eradicating SARS-CoV-2 virus-infected cells.

The FDA has approved VEKLURY (Remdesivir,) developed by Gilead Sciences, Inc., indicated for use in adult and pediatric patients \geq 12 years of age and weighing > 40 kg requiring hospitalization for COVID-19. Other treatments, including convalescent plasma, monoclonal antibodies Bamlanivimab (Eli Lilly) and Casirivimab/Imdevimab (Regeneron), as well as the combination of Baricitinib (JAK/STAT inhibitor from Eli Lilly) with Remdesivir have been granted Emergency Use Authorization (EUA) by the FDA for the treatment of patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. Finally, the Pfizer/BioNTech and Moderna preventative vaccines have been granted EUA. Pfizer's vaccine for individuals 16 years of age and older, while Moderna's vaccine is authorized for emergency use to prevent COVID-19 in those 18 years of age and older. There are several antiviral therapies and vaccines in clinical development, but there are currently no other FDA-approved or authorized antiviral therapies for the treatment or prevention of SARS-CoV-2 infections.

ALVR109

ALVR109 is a SARS-CoV-2-specific T-cell product candidate comprised of polyclonal (CD4+ and CD8+) VSTs which is generated from healthy, eligible seropositive donors and targets immunogenic viral antigens. As illustrated below, preclinical *in vitro* data developed pursuant to the BCM SRA indicated that ALVR109 demonstrated selective cytolytic activity against target cells presenting SARS-CoV-2 antigens while leaving non-virus infected targets intact.

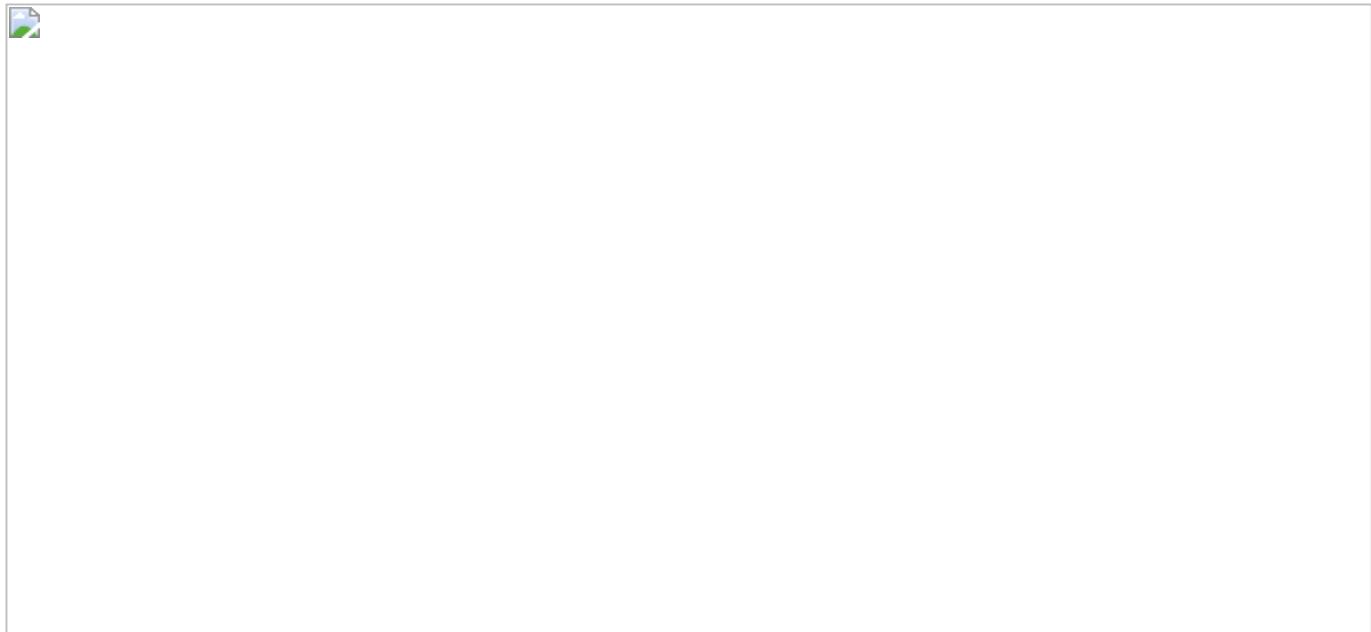


Figure 18. ALVR109 Has Demonstrated Selective Cytolytic Activity against SARS-CoV-2 While Leaving Non-Virus Infected Targets Intact

In addition to targeting SARS-CoV-2, due to homology against CoV strains, we believe this investigational therapy may also address other family members, including SARS-CoV, MERS-CoV, and endemic CoVs that commonly afflict immunocompromised patients. ALVR109 is designed to be used at the point-of-care at the time of diagnosis to provide immediate T-cell immune support.

The development of ALVR109 demonstrates our ability to rapidly and efficiently develop new VST therapy candidates in response to emerging viral pathogens. Our approach of delivering high-risk patients with banks of *ex vivo*-expanded, VST therapies generated from healthy immune donors is designed to address the underlying immune deficiency. Furthermore, VST therapies are prospectively prepared and thus immediately available as an off-the-shelf therapy. These VST therapies are polyclonal and target multiple virus-expressed antigens, which we believe makes them less susceptible to viral point mutations that typically confer drug resistance. We believe these features distinguish our approach from others currently in development.

Clinical Development Plan

Pursuant to the BCM SRA, in its capacity as trial sponsor, BCM initiated a proof-of-concept trial in the fourth quarter of 2020, with top-line data expected in 2021. This trial is actively recruiting and ongoing.

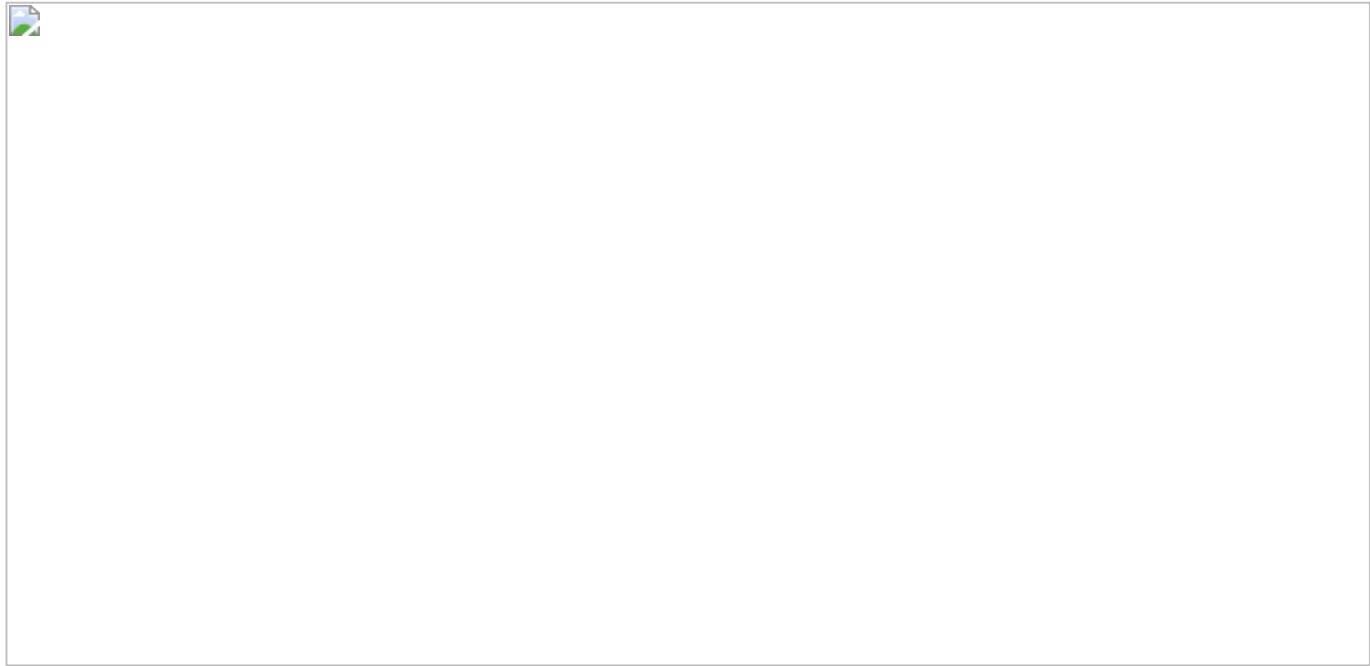


Figure 19. Proposed ALVR109 proof-of-concept trial design

ALVR107: VST Therapy for the Treatment of Hepatitis B Virus

Hepatitis B Virus

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

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

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

ALVR107

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

Clinical Development Plan

We plan to complete pre-clinical IND enabling studies for ALVR107 in the second half of 2021.

ALVR108: VST Therapy for the Treatment of Human Herpesvirus-8

Human Herpesvirus-8

Human herpesvirus-8, or HHV-8, is a herpesvirus that establishes life-long latency after primary infection. The seroprevalence of HHV-8 is estimated to be between 1-5% in the United States, 10-20% in certain Mediterranean countries, and 30-80% in parts of sub-Saharan Africa. Though primary HHV-8 infection is usually asymptomatic, reactivation in immunocompromised individuals, such as those infected with human immunodeficiency virus, or HIV, or transplant patients can result in diseases, including Kaposi Sarcoma, or KS, primary effusion lymphoma, or PEL, and multicentric Castleman's disease, or MCD.

KS is a type of cancer that develops from the cells that line lymph or blood vessels and can progress rapidly resulting in high mortality rates in those with advanced disease. For HIV-AIDS-related KS, first line treatment involves antiretroviral therapy, or ART, to reduce the HIV viral load and support immune recovery. In non-ART-responders systematic pegylated liposomal doxorubicin, has resulted in response rates of approximately 45%. Paclitaxel has produced higher response rates (approximately 55-70%) but is also more toxic, and therefore usually is reserved for second-line systemic therapy. Since HHV-8 cannot be cured by existing treatments, tumors may recur. As a result, novel therapies are needed to address this unmet medical need.

PEL is a rare and aggressive type of non-Hodgkin lymphoma, or NHL caused by HHV-8 infection. The disease most commonly presents as malignant effusions of the body and represents approximately 4% of all NHL cases. There is no standard treatment for PEL, which is resistant to cytotoxic therapies, and the prognosis for patients with PEL remains extremely poor with median survival of less than six months underscoring the need for novel therapies.

MCD is a systemic form of Castleman's disease that affects multiple lymph nodes throughout the body and has been associated with HHV-8 reactivation in approximately 50% of cases. The symptoms of MCD include enlarged lymph nodes, fever, weight loss, nausea, rash, and/or an enlarged liver and spleen and range in severity from mild and nonspecific to life threatening. Treatment of MCD is challenging, and no single treatment works for all people with the disease.

ALVR108

ALVR108 is an allogeneic, off-the-shelf VST therapy designed to target HHV-8. ALVR108 is comprised of a bank of VSTs manufactured from eligible third-party healthy donors who are pre-screened for infectious agents and disease risk factors. These donors are chosen to reflect and accommodate the HLA diversity of the patient population. ALVR108 may be provided to patients who are at risk of developing KS, PEL, or MCD.

Preclinical data have demonstrated that ALVR108 has potent antiviral activity against HHV-8.

Clinical Development Plan

We plan to complete pre-clinical IND enabling studies for ALVR108 in the second half of 2021.

Competition

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

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

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, or are less expensive than any products that we may develop. Our competitors may also obtain FDA or other regulatory approval for their products faster than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated.

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

Cell Therapies

There are currently no FDA- or EMA-approved cell therapies for treating or preventing the viral diseases and infections we are targeting. Atara Biotherapeutics, Inc. is conducting Phase 3 clinical trials for tabelecleucel (tab-cel®), an off-the-shelf, allogeneic T-cell immunotherapy, for HSCT and SOT patients with EBV+PTLD (EBV-associated post-transplant lymphoproliferative disease).

Antivirals

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

Viralym-M (ALVR105): With the exception of valganciclovir, ganciclovir and letermovir for the prevention of CMV disease, there are no products FDA-approved for the treatment of AdV, EBV, BKV, HHV-6, or CMV infections or their consequent diseases in allogeneic HSCT or SOT patients. Certain approved generic antiviral medications, including foscarnet, are used off-label to treat CMV infections in HSCT and SOT patients. Furthermore, there are currently no FDA- or EMA-approved antiviral therapies for the prevention of multiple-viral diseases or infections in transplant patients. Cidofovir is sometimes used off-label for the treatment of BKV-associated HC and AdV infections in HSCT patients. Additionally, Amlyx Pharmaceuticals, Inc. is planning Phase 2 clinical trials for MAU868 for the prevention and/or treatment of BKV in HSCT and KT patients. Takeda Pharmaceutical Company, or Takeda, has concluded its Phase 3 clinical trials of maribavir to treat CMV infection in HSCT and SOT patients. Helocyte, Inc. is conducting Phase 2 clinical trials of its Triplex vaccine to control CMV infections in HSCT patients. Rituximab, an approved antiviral treatment for rheumatoid arthritis and B-cell non-Hodgkin's lymphoma, is used off-label for the treatment of EBV infections in HSCT and SOT patients. Brincidofovir, a lipid conjugate of cidofovir, is in early development by SymBio Pharmaceuticals for the treatment of viral HC and HHV-6 encephalitis after allogeneic HSCT. Finally, intravenous immunoglobulin (IVIG) has been explored for the prevention and treatment of BKV associated nephropathy in renal transplant patients, but not in HSCT patients. Even in renal transplant patients, there is limited efficacy data for IVIG to support routine use.

ALVR106: The FDA has approved ribavirin (aerosol) to treat RSV infections in children and pavilizumab to treat RSV infections in children younger than two years old. Ribavirin is also used off-label for the treatment or prevention of RSV infections in HSCT and SOT patients and PIV infections and hMPV infections in HSCT patients. AstraZeneca is conducting Phase 3 clinical studies of nirsevimab to treat RSV infections and ADMA Biologics, Inc. is conducting Phase 2 clinical trials of RI-002 to treat RSV infections in immunocompromised patients. Certain approved generic antiviral medications, including oseltamivir, zanamivir and baloxavir, are used off-label to treat Influenza infections in HSCT and SOT patients. Ansun BioPharma, or Ansun, is conducting Phase 2 clinical trials of DAS181 to treat Influenza infections. Several vaccines are FDA-approved and in clinical development for the prevention of Influenza infections. Ansun is also conducting Phase 3 clinical studies of DAS181 to treat PIV infections and Phase 1 clinical studies of DAS181 to treat hMPV infections.

ALVR109: The FDA has approved VEKLURY (Remdesivir,) developed by Gilead Sciences, Inc., indicated for use in adult and pediatric patients >-12 years of age and weighing > 40 kg requiring hospitalization for COVID-19. Several modalities including convalescent plasma, monoclonal antibodies Bamlanivimab (Eli Lilly) and Casirivimab/Imdevimab (Regeneron), as well as the combination of Baricitinib (JAK/STAT inhibitor from Eli Lilly) with Remdesivir have been granted Emergency Use Authorization (EUA) by the FDA for the treatment of patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. Finally, the Pfizer/BioNTech vaccine has been granted EUA for individuals 16 years of age and older, while Moderna's vaccine is authorized for emergency use to prevent COVID-19 in those 18 years of age and older.

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

ALVR108: There are currently no antiviral therapies approved by the FDA or in clinical development for the treatment or prevention of HHV-8 infections.

Intellectual Property

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

As of January 31, 2021, our patent portfolio includes eight patent families exclusively in-licensed from Baylor College of Medicine, or BCM, in our field (one of which is co-owned by AlloVir). These families include issued and pending patents related generally to our allogeneic, off-the-shelf, multi-VST cell therapies, our clinical product candidates Viralym M (ALVR105), ALVR106, and ALVR109, various pre-clinical product candidates, and our current clinical and backup processes for generating VST cell products and banks. Specifically, we have exclusively in-licensed at least 2 issued US patents, 30 patents issued in foreign jurisdictions, and 22 patent applications pending worldwide. Our issued patents are expected to expire between 2030 and 2033, and any patents that may issue from our pending patent applications are expected to expire between 2030 and 2041, absent any patent term adjustments or extensions. As to the patent term extension to restore patent term lost during product development and the FDA regulatory review process, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval.

Our portfolio related to our Viralym M product candidate includes two patent families directed to multi-VST compositions and methods of making and using such compositions therapeutically. The first family includes two issued U.S. patents with claims directed to our clinical and backup methods of making multi-VST cell lines and related patent applications are pending in the U.S. and Europe. Patents in this family are expected to expire in 2030, absent any patent term adjustments or extensions. The second family includes an issued European patent with claims directed to methods of making multi-VST compositions including Viralym M and ALVR106. This patent is validated in 19 European states including Denmark, France, Germany, Spain and the UK. Related patent applications are pending in the U.S. and in Europe. Patents in this family are expected to expire in 2033, absent any patent term adjustments or extensions as noted above.

Our portfolio related to our ALVR106 product candidate includes the two patent families discussed above with respect to Viralym M as well as a pending international application filed under the Patent Cooperation Treaty (PCT) with claims directed to the ALVR106 product and method of making and using the same therapeutically. Any patents that may issue from this patent application are expected to expire in 2040, absent any patent term adjustments or extensions.

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

Our portfolio further includes other patent families related to our VST technologies. For example, our portfolio includes one patent family consisting of a pending PCT application related to our process of selecting donors for VST generation and our methods of matching patients with suitable VST cell lines; one patent family with pending patent applications directed to methods of identifying peptides that are likely to be immunogenic; and one patent family consisting of patents and pending patent applications with claims directed to methods of rapidly expanding T-cells. Patents in the T-cell expansion family are expected to expire in 2032, and any patents that may issue from the immunogenicity family or from the pending PCT application are expected to expire in 2036 and 2040, respectively, absent any patent term adjustments or extensions.

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

We also rely on trade secrets relating to product candidates and seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. It is our policy to require our employees, consultants, outside scientific partners, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course

of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees and consultants also provide that all inventions conceived by the employee or consultant in the course of employment or consulting relationships with us or from the employee's or consultant's use of our confidential information are our exclusive property and require such employees and consultants to assign their title, right and interest in such inventions to us. Although we take steps to protect our proprietary information and trade secrets, including through such contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, including through breaches of such agreements with our employees and consultants. Thus, we may not be able to meaningfully protect our trade secrets.

Sponsored Research, Collaboration and License Agreements

Amended and Restated Exclusive License Agreement with BCM

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

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

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

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

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

Exclusive License Agreement with BCM

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

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

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

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

Sponsored Research Agreement with BCM

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

Collaboration Agreement with BCM

In November 2020, we entered into a Research Collaboration Agreement, or the Research Agreement, with BCM, under which we agreed to pay BCM for performing certain research activities under the direction of Dr. Ann Leen commencing on January 1, 2021 and continuing for a three-year period thereafter. The Research Agreement requires us to make payments to BCM totaling approximately \$2.0 million per year, for a total of \$6.0 million over the term of the Research Agreement.

Manufacturing

Our efficient and versatile VST manufacturing platform supports the rapid, robust and scalable generation of single- and multi-virus specific cell therapeutic candidates for clinical use. We leverage Cytokin™, our proprietary algorithm for donor selection, to efficiently identify donors from whom to generate VSTs that provide broad patient coverage. Virus-specific T-cell populations are expanded in a fully good manufacturing practices, or cGMP, compliant process, which is scaled to produce hundreds of cell doses from each manufacturing run. These cells are maintained in a cryopreserved state ready for “off-the-shelf” use in combination with our Cytomatch™ algorithm, which guides the selection of VST therapy for patient. In combination, these elements allow us to efficiently build our global supply chain to serve a growing number of patients that could benefit from our highly innovative off-the-shelf VST therapy candidates.

To facilitate drug supply for our proposed Viralym-M, ALVR106 and ALVR109 clinical trials, we are currently manufacturing our Viralym-M and ALVR106 VSTs at an external cGMP CMO and ALVR109 at an academic cGMP facility. We believe this approach for our clinical product candidates is cost-effective and has allowed us to rapidly prepare for clinical trials in accordance with our development plans.

Additionally, as an ElevateBio affiliate, we are also able to leverage ElevateBio's expertise to rapidly and efficiently manufacture VST therapies. ElevateBio has established BaseCamp, a centralized cell and gene therapy manufacturing facility dedicated to the production of products for its affiliated companies. As we advance our clinical trials over the next year we will further expand our raw material suppliers and leverage the substantial cell therapy manufacturing expertise and state-of-the-art facility of ElevateBio to increase manufacturing capacity to serve our global patient population.

Government Regulation

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

U.S. Biological Products Development Process

The process required by the FDA before a biological product may be marketed in the United States generally involves the following:

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

Before testing any biological product candidate, in humans, the product candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product biological characteristics, chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLPs.

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

In addition to the submission of an IND to the FDA before initiation of a clinical trial in the United States, certain human clinical trials involving recombinant or synthetic nucleic acid molecules are subject to oversight of institutional biosafety committees, or IBCs, as set forth in the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, or NIH Guidelines. Specifically, under the NIH Guidelines, supervision of human gene transfer trials includes evaluation and assessment by an IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment, and such review may result in some delay before initiation of a clinical trial. While the NIH Guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them.

Clinical trials involve the administration of the biological product candidate to healthy volunteers or patients under the supervision of qualified investigators which generally are physicians not employed by, or under, the control of the trial sponsor. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur.

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

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

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

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

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

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

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

U.S. Review and Approval Processes

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

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review to determine if it is substantially complete before the FDA accepts it for filing. In most cases, the submission of a BLA is subject to a substantial application user fee, although the fee may be waived under certain circumstances. Under the performance goals and policies implemented by the FDA under the Prescription Drug User Fee Act, or PDUFA, for original BLAs, the FDA targets ten months from the filing date in which to complete its initial review of a standard application and respond to the applicant, and six months from the filing date for an application with priority review. The FDA does not always meet its PDUFA goal dates, and the review process is often significantly extended by FDA requests for additional information or clarification.

Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, for its intended use, and whether the product is being manufactured in accordance with cGMP to ensure its continued safety, purity and potency. The FDA may refer applications for novel biological products or biological products that present difficult or novel questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

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

Under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA for a novel product (e.g., new active ingredient, new indication, etc.) must contain data to assess the safety and effectiveness of the biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

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

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

Orphan Drug Designation

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

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research and a waiver of the BLA application user fee.

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

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

Expedited Development and Review Programs

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

Under the FDA's breakthrough therapy program, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough therapy designation comes with all of the benefits of fast track designation, which means that the sponsor may file sections of the BLA for review on a rolling basis if certain conditions are satisfied, including an agreement with the FDA on the proposed schedule for submission of portions of the application and the payment of applicable user fees before the FDA may initiate a review. The FDA may take other actions appropriate to expedite the development and review of the product candidate, including holding meetings with the sponsor and providing timely advice to, and interactive communication with, the sponsor regarding the development program.

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

Additionally, a product candidate may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on an intermediate clinical endpoint other than survival or irreversible morbidity, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA generally requires that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials to verify the clinical benefit in relationship to the surrogate endpoint or ultimate outcome in relationship to the clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. The FDA may withdraw approval of a drug or indication approved under accelerated approval if, for example, the confirmatory trial fails to verify the predicted clinical benefit of the product.

RMAT Designation

As part of the 21st Century Cures Act, enacted in December 2016, Congress created the Regenerative Medicine Advanced Therapy, or RMAT, designation to facilitate an efficient development program for, and expedite review of, a product candidate that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. A sponsor may request that the FDA designate a drug as a RMAT concurrently with or at any time after submission of an IND. The FDA has 60 calendar days to determine whether the drug meets the criteria. A BLA for a regenerative medicine therapy that has received RMAT designation may be eligible for priority review or accelerated approval through use of surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites. Benefits of RMAT designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy with RMAT designation that is granted accelerated approval and is subject to post-approval requirements may, as appropriate, fulfill such requirements through the submission of clinical evidence from clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all patients treated with such therapy prior to its approval. Like some of FDA's other expedited development programs, RMAT designation does not change the standards for approval but may help expedite the development or approval process.

Post-approval Requirements

Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements, as well as requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. We currently rely, and may continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-approval requirements applicable to biological products, include reporting of cGMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse effects, reporting updated safety and efficacy information, and complying with electronic record and signature requirements. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for

distribution. After a BLA is approved for a biological product, the product also may be subject to official lot release. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA also may perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, and effectiveness of biological products.

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

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

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including withdrawal of the product from the market. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of the use of our product candidates, some of our United States patents may be eligible for limited patent term extension under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. In addition, a patent can only be extended once and only for a single product. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may intend to apply for restoration of patent term for one of our patents, if and as applicable, to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA.

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

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

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

In addition to exclusivity under the BPCIA, a biological product can obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods, including some regulatory exclusivity periods tied to patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued “Written Request” for such a study.

Additional Regulation

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

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

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

Our operations are also subject to non-United States anti-corruption laws such as the U.K. Bribery Act 2010, or the Bribery Act. As with the FCPA, these laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense.

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

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

Government Regulation Outside of the United States

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

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

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

Clinical Trials Regulation

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted for each clinical trial to each country's National Competent Authority, or NCA, and at least one independent Ethics Committee, or EC, much like the FDA and an IRB, respectively. Once the CTA is approved in accordance with a country's requirements, the corresponding clinical trial may proceed. Under the current regime (the EU Clinical Trials Directive 2001/20/EC and corresponding national laws) all suspected unexpected serious adverse reactions to the investigational drug that occur during the clinical trial have to be reported to the NCA and ECs of the European Union Member State where they occurred.

In April 2014, the European Union adopted a new Clinical Trials Regulation (EU) No 536/2014, which is set to replace the current Clinical Trials Directive 2001/20/EC. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new Clinical Trials Regulation, which will be directly applicable in all Member States (meaning that no national implementing legislation in each European Union Member State is required), aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new Clinical Trials Regulation provides for a streamlined application procedure via a single entry point and strictly defined deadlines for the assessment of clinical trial applications. It is expected that the new Clinical Trials Regulation will come into effect following confirmation of full functionality of the Clinical Trials Information System, the centralized European Union portal and database for clinical trials foreseen by the new Clinical Trials regulation, through an independent audit, which is currently expected to occur in December 2021.

Drug Review and Approval

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

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

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

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

Data and Marketing Exclusivity

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

Orphan Drug Designation and Exclusivity

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

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as an orphan medicinal product if it meets the following criteria: (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either the prevalence of such condition must not be more than five in 10,000 persons in the European Union when the application is made, or without the benefits derived from orphan status, it must be unlikely that the marketing of the medicine would generate sufficient return in the EEA to justify the investment needed for its development; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EEA, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

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

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

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

Pediatric Development

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

PRIME Designation

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

Post-Approval Controls

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

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

Brexit and the Regulatory Framework in the United Kingdom

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

Coverage and Reimbursement

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

There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. Factors a payor considers in determining reimbursement are based on whether the product is:

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

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

Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

Other Healthcare Laws and Compliance Requirements

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

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; a person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute;
- the federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the False Claims Act. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery;
- the Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious, or fraudulent statements or representations in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys’ fees and costs associated with pursuing federal civil actions;
- the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which require applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs;

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

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

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

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

Data Privacy and Security Laws

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

In addition, certain states govern the privacy and security of health information and/or other personally identifiable information, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California recently enacted the 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 requires 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/or that is collected, used, or disclosed in clinical trial research, as currently written, the CCPA may still impact our business activities. The uncertainty and enforcement surrounding the implementation of CCPA exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

Additionally, a new California ballot initiative, the California Privacy Rights Act, or “CPRA,” was passed in November 2020. Effective starting on January 1, 2023, the CPRA imposes additional obligations on companies covered by the legislation and will significantly modify the CCPA, including by expanding consumers’ rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The effects of the CCPA and the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and increase our potential exposure to regulatory enforcement and/or litigation.

Certain other state laws impose similar privacy obligations and we also expect anticipate that more states to may enact legislation similar to the CCPA, which provides consumers with new privacy rights and increases the privacy and security obligations of entities handling certain personal information of such consumers. The CCPA has prompted a number of proposals for new federal and state-level privacy legislation. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies.

The 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 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. Further to the United Kingdom's (UK) exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law (referred to as the 'UK GDPR'). The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. The UK, however, is now regarded as a third country under the EU's GDPR which means that transfers of personal data from the EEA to the UK will be restricted unless an appropriate safeguard, as recognized by the EU's GDPR, has been put in place. Although, under the EU-UK Trade Cooperation Agreement it is lawful to transfer personal data between the UK and the EEA for a 6 month period following the end of the transition period, with a view to achieving an adequacy decision from the European Commission during that period. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection (this means that personal data transfers from the UK to the EEA remain free flowing). Compliance with the GDPR and UK 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 or UK activities.

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

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the ACA, was enacted which includes changes to the coverage and payment for products under government health care programs. Among other things, the ACA:

- increases the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program;
- addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extends the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans;
- establishes annual fees and taxes on manufacturers of certain branded prescription drugs;
- creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.; and
- expands the entities eligible for discounts under the PHS Act's pharmaceutical pricing program, also known as the 340B Drug Pricing Program.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, some laws affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision that decreased, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate," to \$0. On December 14, 2018, a District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit U.S. Court of Appeals held the individual mandate unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. It is unclear what effect this will have on the status of the ACA and our business. Congress may also consider other legislation to repeal or replace certain elements of the ACA.

In addition, since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, on October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On April 27, 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. The Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to legislation amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will stay in effect through 2030, unless additional Congressional action is taken. However, the Medicare sequester reductions under the Budget Control Act have been suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. Proposed legislation, if passed, would extend this suspension until the end of the COVID-19 pandemic. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. In addition, CMS published a final rule that would give states greater flexibility, as of 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. The Trump administration also previously released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In addition, there has been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs ("SCODs"). The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any. While a number of these and other proposed measures will require authorization through additional legislation to become effective, Congress has each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

Additionally, 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 medicines from countries where they may be sold at lower prices than in the U.S. President Trump has signed several Executive Orders aimed at lowering drug prices. On July 24, 2020, President Trump signed Executive Orders directing the Secretary of HHS to: (1) eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of the FDA's December 2019 proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) allow certain low-income individuals receiving insulin and epinephrine purchased by a Federally Qualified Health

Center as part of the 340B drug pricing program to purchase those drugs at the discounted price paid by the Federally Qualified Health Center. The FDA published a final rule, effective November 30, 2020, that allows for the importation of certain prescription drugs from Canada. Under the final rule, states and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for “best price” or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country.

On September 13, 2020, President Trump signed an Executive Order directing HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug or biologic manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. In response, HHS on (i) November 20 2020 issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge; and (ii) November 20, 2020, finalized a regulation removing the safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Employees

As of December 31, 2020, we had 53 full-time employees, including 10 with Ph.D. or M.D. degrees, and 34 who are engaged in research and development activities. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

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

Available Information

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

Item 1A. Risk Factors.

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

Risks Related to Current Novel Coronavirus (COVID-19) Pandemic

Our business could be adversely affected by the effects of health epidemics, including the recent COVID-19 pandemic, in regions where third parties for which we rely, as in 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 CROs 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. On January 30, 2020, the World Health Organization, or WHO, announced a global health emergency because of SARS-CoV-2, a new strain of novel coronavirus originating in Wuhan, China, and the risks to the international community as the virus spread globally beyond its point of origin. In March 2020, the WHO declared the COVID-19 outbreak a pandemic, which continues to spread throughout the world. The spread of this pandemic has caused significant volatility and uncertainty in U.S. and international markets. This could result in an economic downturn and may disrupt our business and delay our clinical programs and timelines.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Any manufacturing supply interruption of materials could adversely affect our ability to conduct ongoing and future research and manufacturing activities.

In addition, our clinical trials may be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of healthcare system resources toward the COVID-19 pandemic. Some patients may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, the ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and adversely impact our clinical trial operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 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 spread of COVID-19 could materially affect our business and the value of our common stock.

Two vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020, and more are likely to be authorized in the coming months. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials.

The global pandemic of COVID-19 continues to rapidly evolve. 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 COVID-19 situation closely.

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;
- establish and maintain 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;
- establish and qualify 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;
- attract, hire and retain 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;
- protect our rights in our intellectual property portfolio;
- 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, Viralym-M, ALVR106, and ALVR109. 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; or
- changes in the approval policies or regulations that render our preclinical and clinical data insufficient for approval.

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, 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- or EMA-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 other government agencies 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. 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.

Additionally, as of June 23, 2020, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, FDA may not be able to continue its current pace and approval timelines could be extended, including where a pre-approval manufacturing inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. On March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities while local, national and international conditions warrant. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials which the FDA continues to update. As of June 23, 2020, the FDA noted it was conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. On July 10, 2020, the FDA announced its goal of restarting domestic on-site inspections during the week of July 20, 2020, but such activities will depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. In 2020, several companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If the FDA becomes unable to continue its current level of performance, we could experience delays and setbacks for our product candidates and for any approvals we may seek which could adversely affect our business.

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 Tissues and Advanced Therapies 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, such as on account of the COVID-19 pandemic and its impact at clinical trials sites or on the third-party service providers on whom we rely. In July 2020, the IND that 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 contract research organizations, or 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, including due to impacts from the COVID-19 pandemic on their workforce;
- 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, including on account of the COVID-19 pandemic;
- 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;
- travel restrictions and other potential limitations by federal, state, or local governments affecting the workforce or affecting clinical research site policies implemented in response to the COVID-19 pandemic;
- delays in or temporary suspension of the enrollment of patients in our ongoing and planned clinical trials due to the COVID-19 pandemic;
- 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, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. We could also 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 a single CRO, 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 planned Phase 3 pivotal and Phase 2 proof-of-concept clinical trials of Viralym-M, 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 Viralym-M, ALVR106, ALVR109 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, all 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 Viralym-M 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, “top line” 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 “top line” or preliminary data from our clinical trials, which is 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 top-line 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 “top line” data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. As a result, interim, “top-line,” and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary, “top-line,” 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, “top-line,” 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.

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. In the European Union, the prevalence of the condition must not be more than 5 in 10,000. The EMA has granted Viralym-M orphan drug designation to treatment in HSCT. This designation covers the treatment of all viruses targeted by Viralym-M in all HSCT 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.

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, 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 Viralym-M are based on estimates and third-party sources. If the market opportunity for Viralym-M 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 Viralym-M will depend on, among other things, acceptance of Viralym-M 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 Viralym-M, 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 HSCT, 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 HSCT patients, for Viralym-M. 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 Viralym-M for the treatment of HC caused by BKV in adults and children following allogeneic HSCT. 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 HSCT 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.

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.

Failure to obtain regulatory approval in international jurisdictions would prevent our product candidates from being marketed abroad.

In addition to regulations in the United States, to market and sell our products in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished.

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, quality control, further development, labeling, packaging, storage, distribution, 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. 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.

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.

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. Factors a payor considers in determining reimbursement are based on whether the product is:

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

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. Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

Our business is highly dependent on our lead product candidate, Viralym-M, 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 our planned Phase 3 clinical trial of Viralym-M will be sufficient to obtain regulatory approval or marketing authorization for such product candidate. 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. In particular, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively, the Affordable Care Act, or ACA, was enacted, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act and its implementing regulations, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for certain drugs and biologics, including our product candidates, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, provided incentives to programs that increase the federal government's comparative effectiveness research and established a new Medicare Part D coverage gap discount program.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed comprehensive repeal legislation, some laws affecting the implementation of certain taxes under the ACA have been signed into law. For example, the Tax Cuts and Jobs Act of 2017, or TCJA, includes a provision that decreased, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate," to \$0. On December 14, 2018, a District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The current administration and CMS have both stated that the ruling will have no immediate effect, and on December 18, 2019, the Fifth Circuit U.S. Court of Appeals held the individual mandate unconstitutional, and remanded the case to the lower court to reconsider its earlier invalidation of the full ACA. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. It is unclear what effect this will have on the status of the ACA and our business. Congress may also consider other legislation to repeal or replace certain elements of the ACA.

In addition, since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. On January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, on October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the U.S. Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On April 27, 2020, the United States Supreme Court reversed the U.S. Court of Appeals for the Federal Circuit decision and remanded the case to the U.S. Court of Federal Claims, concluding the government has an obligation to pay these risk corridor payments under the relevant formula.

It is unclear how this litigation or other efforts to repeal and replace the Affordable Care Act will impact the law or our business. The U.S. Congress may consider and adopt other legislation to repeal and replace all or certain elements of the ACA. Any other executive, legislative or judicial action to "repeal and replace" all or part of the ACA may have the effect of limiting the amounts that government agencies will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure, or may lead to significant deregulation, which could make the introduction of competing products and technologies much easier. Policy changes, including potential modification or repeal of all or parts of the ACA or the implementation of new health care legislation, could result in significant changes to the health care system which may adversely affect our business in unpredictable ways.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, and subsequent legislation, have suspended these reductions from May 1, 2020 through March 31, 2021. Proposed legislation, if passed, would extend this suspension until the end of the COVID-19 pandemic. In addition, in January 2013, the American Taxpayer Relief Act of 2012, or the ATRA, was enacted which, among other things, further reduced Medicare payments to several providers, including hospitals and outpatient clinics, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of the federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. In addition, CMS published a final rule that would give states greater flexibility, as of 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to request access to certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare, including by imposing price controls, may adversely affect the demand for our product candidates for which we obtain regulatory approval and our ability to set a price that we believe is fair for our products. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of these changes on the regulatory approvals of our product candidates, if any, may be. In the U.S., the European Union and other potentially significant markets for our product candidates, government authorities and third-party payors are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices for certain products in certain markets. For example, in the U.S., there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a \$135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. The Trump administration also previously released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In addition, there has been several changes to the 340B drug pricing program, which imposes ceilings on prices that drug manufacturers can charge for medications sold to certain health care facilities. On December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change under the 340B drug pricing program, and CMS subsequently altered the FYs 2019 and 2018 reimbursement formula on specified covered outpatient drugs ("SCODs"). The court ruled this change was not an "adjustment" which was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation. However, most recently, on July 31, 2020, the U.S. Court of Appeals for the District of Columbia Circuit overturned the district court's decision and found that the changes were within the Secretary's authority. On September 14, 2020, the plaintiffs-appellees filed a Petition for Rehearing En Banc (i.e., before the full court), but was denied on October 16, 2020. It is unclear how these developments could affect covered hospitals who might purchase our future products and affect the rates we may charge such facilities for our approved products in the future, if any.

Lastly, on July 24, 2020 and September 13, 2020, President Trump signed several Executive Orders aimed at lowering drug prices. On July 24, 2020, President Trump signed Executive Orders directing the Secretary of HHS to: (1) eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of the FDA's December 2019 proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) allow certain low-income individuals receiving insulin and epinephrine purchased by a Federally Qualified Health Center as part of the 340B drug pricing program to purchase those drugs at the discounted price paid by the Federally Qualified Health Center. The FDA published a final rule, effective November 30, 2020, that allows for the importation of certain prescription drugs from Canada. Under the final rule, states and Indian Tribes, and in certain future circumstances pharmacists and wholesalers, may submit importation program proposals to the FDA for review and authorization. On September 25, 2020, CMS stated drugs imported by States under this rule will not be eligible for federal rebates under Section 1927 of the Social Security Act and manufacturers would not report these drugs for "best price" or Average Manufacturer Price purposes. Since these drugs are not considered covered outpatient drugs, CMS further stated it will not publish a National Average Drug Acquisition Cost for these drugs. Separately, the FDA also issued a final guidance document outlining a pathway for manufacturers to obtain an additional National Drug Code, or NDC, for an FDA-approved drug that was originally intended to be marketed in a foreign country and that was authorized for sale in that foreign country.

On September 13, 2020, President Trump signed an Executive Order directing HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug or biologic manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. In response, HHS on (i) November 20 2020 issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge; and (ii) November 20, 2020, finalized a regulation removing the safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. It is unclear if, when, and to what extent the Executive Orders may be further implemented. The regulatory and market implications of the Executive Orders are unknown at this time, but legislation, regulations or policies allowing the reimportation of drugs may decrease the price we receive for our products and adversely affect our future revenues and prospects for profitability. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved medicines we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize medicines, and our overall financial condition.

Although some of these and other proposals may require additional authorization to become effective, members of Congress have indicated that they will continue to seek new legislative or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing. Furthermore, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general.

In addition, there is significant uncertainty regarding the reimbursement status of newly approved healthcare products. We may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. If third-party payors do not consider our products to be cost-effective compared to other therapies, the payors may not cover our products after approved as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

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. Restrictions under applicable federal and state healthcare laws and regulations that may affect our ability to operate include the following:

- the federal healthcare Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving, paying or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, arrangement, or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers, among others, on the other;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to, or approval by, Medicare, Medicaid, or other federal healthcare programs, knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government, or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. Manufacturers can be held liable under the False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The False Claims Act also permits a private individual acting as a “whistleblower” to bring actions on behalf of the federal government alleging violations of the False Claims Act and to share in any monetary recovery
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious, or fraudulent statements in connection with the delivery of or payment for healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal transparency requirements under the Affordable Care Act, or ACA, including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers or patients; state laws that require pharmaceutical companies to comply with the industry’s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; and state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

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, receive, 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. The California Attorney General has proposed draft regulations, which have not been finalized to date, that may further impact our business activities if they are adopted. 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 jurisdiction 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 Chief Executive, 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, 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 our affiliate, ElevateBio. For instance, David Hallal serves as Chief Executive Officer 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 Cambridge, Massachusetts and Houston, Texas. Both 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. The value to employees of restricted stock and stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. 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.

We are an affiliate of ElevateBio. David Hallal, our Chairman and Chief Executive, also serves as the Chairman Chief Executive Officer of ElevateBio, and Vikas Sinha, our Chief Financial Officer, also serves as the Chief Financial Officer of ElevateBio. Ansbert Gadicke and Morana Jovan-Embiricos, two members of our board of directors also serve as directors 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 December 31, 2020, we had 53 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 cyberattacks, 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 for 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 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.

Legislation or other changes in U.S. tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. 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.

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

Our ability to use our U.S. federal and state 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 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 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 losses 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, 2020, we had U.S. federal net operating loss carryforwards of approximately \$20.9 million, and 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.

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

Global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, 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.

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 reasonable 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 \$69.8 million and \$23.8 million for the years ended December 31, 2020 and 2019. As of December 31, 2020, we had an accumulated deficit of \$125.1 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, Viralym-M, for our initial and potential additional indications;
- initiate and continue research, preclinical and clinical development efforts for our additional product candidates, including ALVR106, ALVR109, ALVR107, ALVR108 and any future product candidates we may develop;
- seek to identify additional product candidates;
- seek regulatory approvals for Viralym-M 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 U.S. Food and Drug Administration, or 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, including as a result of the coronavirus disease 19, or COVID-19, pandemic.

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 Viralym-M, ALVR106, ALVR109 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 and our initial public offering, or IPO, in August 2020. 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 Viralym-M, 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 Baylor College of Medicine, or 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 COVID-19-related program setbacks or 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 Viralym-M for our initial and potential additional indications, as well as ALVR106, ALVR109 and other product candidates we may develop, including any COVID-19-related delays or other effects on our development programs;
- the timing of, and the costs involved in, obtaining marketing approvals for Viralym-M 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 Viralym-M 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 Viralym-M 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 \$356.3 million as of December 31, 2020. 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 the net proceeds from our IPO, together with our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements into 2023. 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 Ownership of our Common Stock

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 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, including impacts from the COVID-19 pandemic; 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 65% of our common stock as of December 31, 2020. 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, 2021 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 \$1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will 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 Securities and Exchange Commission, or 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 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 Cambridge, 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 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.

Our association with ElevateBio provides access to ElevateBio's BaseCamp cell therapy process development and manufacturing expertise. ElevateBio has established a centralized facility dedicated to the production of cell and gene therapy products for its affiliated companies, eliminating the need for each company to build its own facilities and hire the appropriate expertise and intends become a supplier of our drug product. ElevateBio currently manages all of our current investigational cell therapies at external contract manufacturing organizations, or CMOs and plans to provide additional GMP manufacturing capacity and drug product supply. The facility commissioning and qualification activities required to support production at Base Camp will be completed in 2021. Product-specific qualification to support clinical development and commercial production qualification activities are ongoing. If the appropriate regulatory approvals for at our existing CMO or our facility 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 CMO, BaseCamp, 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 may 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.

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.

The processes by which our product candidates are manufactured were initially developed by our partners for clinical purposes. We intend to evolve the existing processes with our partners to support advanced clinical studies and commercialization requirements. Developing commercially viable 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, 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.

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 Viralym-M, ALVR106, ALVR109 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 our manufacturing facility through our association with ElevateBio 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 not yet identified 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 will be qualified for use in our drug product manufacturing process but 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, including on account of the COVID-19 pandemic, 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 Viralym-M and ALVR106 VSTs at an external cGMP CMO and ALVR109 at an academic cGMP facility, and a single contract testing laboratories 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. Further, the performance of our CROs may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic. 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 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 an exclusive license agreement with BCM for data and know-how, which we refer to as 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 Viralym-M technology prior to the filing of our patent applications covering our Viralym-M 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 Viralym-M 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.

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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

We lease an office space containing a one room suite with workplace capacity for six individuals, which is located in Houston, Texas. The lease expires in March 2021. We additionally sublease a facility from ElevateBio containing 2,879 square feet of office space, which is located in Cambridge Massachusetts. The sublease is based on a month-to-month lease and terminates upon 45 days written notice by us or ElevateBio. We believe that our current facilities are sufficient to meet our current and near-term needs and that, should it be needed, suitable additional space will be available.

Item 3. Legal Proceedings.

From time to time, we may become subject to arbitration, litigation or claims arising in the ordinary course of business. 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 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

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

Holders of Record

As of January 25, 2021, we had approximately 110 holders of record of our common stock. Certain shares are held in “street” name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Recent Sales of Unregistered Securities

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

Use of Proceeds

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

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

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

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

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data.

Not applicable.

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

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

Overview

We are a 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. To date, we have generated five innovative, allogeneic, off-the-shelf VST therapy candidates targeting 12 different devastating viruses. The most advanced is Viralym-M for which we have initiated a pivotal trial for the treatment of virus-associated hemorrhagic cystitis and POC clinical trials for multi-virus prevention in HSCT and BKV in kidney transplant.

As an ElevateBio, LLC, or ElevateBio, affiliate, we are able to leverage ElevateBio's expertise to rapidly and efficiently manufacture VST therapies for clinical trials and commercialization. Our lead product candidate, Viralym-M, is a multi-VST cell therapy that targets five viruses: BK virus, cytomegalovirus, adenovirus, Epstein-Barr virus and human herpesvirus 6. In clinical trials conducted to date, we have treated over 275 allogeneic hematopoietic stem cell transplant, or HSCT, patients with either single or multi-virus targeted allogeneic VSTs and our product candidates have been generally well-tolerated and have been associated with clinical benefit as indicated by the high response rate demonstrated in immunocompromised patients with drug-refractory infections and diseases. To fully explore the clinical benefit of Viralym-M, we plan to initiate a total of three Phase 3 pivotal and three Phase 2 proof-of-concept trials by the end of 2021 for the treatment and prevention of life-threatening viral diseases in pediatric and/or adult patients, each representing a potential meaningful commercial opportunity.

In addition, ALVR106 is our second multi-virus-targeted off-the-shelf VST product candidate targeting devastating respiratory diseases caused by RSV, influenza, PIV and/or hMPV. Our Investigational New Drug, or IND, application with the FDA for ALVR106 was cleared in the fourth quarter of 2020 and we plan to initiate a Phase 1/2 clinical study in autologous and allogeneic HSCT patients with respiratory viral diseases in the 2021-2022 respiratory virus season. Pursuant to our sponsored research agreement with Baylor College of Medicine ("BCM"), BCM initiated a proof-of-concept trial for ALVR109, an allogeneic, off-the-shelf VST therapy designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19. ALVR109 is being developed to arrest the progression of COVID-19 by eradicating SARS-CoV-2 virus-infected cells. BCM initiated the POC clinical trial in the fourth quarter of 2020 and the trial is ongoing and actively recruiting. Lastly, we are also advancing ALVR107 designed to target hepatitis B, or HBV, infected cells and treat chronic HBV infections and ALVR108 to treat human herpesvirus-8, or HHV-8, associated diseases including Kaposi Sarcoma, or KS, primary effusion lymphoma, or PEL, and multicentric Castleman's disease, or MCD. We plan to complete pre-clinical IND enabling studies for ALVR107 and ALVR108 in the second half of 2021. We own worldwide development and commercialization rights to our cell therapies.

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 Viralym-M, ALVR106, ALVR109 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 have funded our operations to date primarily through equity financings and have received proceeds of \$156.3 million, net of issuance costs of \$0.6 million, from the sale of our preferred stock.

We have incurred significant operating losses since inception, including net losses of \$69.8 million and \$23.8 million for the years ended December 31, 2020 and 2019, respectively. At December 31, 2020, we had an accumulated deficit of \$125.1 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, as well as to support our transition to a public reporting company.

We expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential collaborations with other companies or other strategic transactions. Our inability to raise capital as and when needed could have a negative impact on our financial condition and ability to pursue our business strategies. There can be no assurances, however, that the current operating plan will be achieved or that additional funding will be available on terms acceptable to us, or at all.

At December 31, 2020, we had cash, cash equivalents and short-term investments of \$356.3 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 into 2023. 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 recent COVID-19 pandemic. The spread of COVID-19 has impacted the global economy and has impacted 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 has delayed clinical trials. If the disruption due to the COVID-19 pandemic continues, our planned pivotal clinical trials also could be delayed due to government orders and site policies on account of the 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 contract research organizations, or CROs, as well as those of companies with which we do business, including our suppliers and contract manufacturing organizations, or CMOs, thereby disrupting our business operations. Quarantines and travel restrictions imposed by governments in the jurisdictions in which we and the companies with which we do business operate could materially impact the ability of employees to access preclinical and clinical sites, laboratories, manufacturing sites and offices. We have implemented work-at-home policies and only employees essential to the development and research of our product candidates remain on-site at our research and manufacturing facilities; accordingly, we may experience limitations in employee resources. The outbreak and any other preventative or protective actions that we, our suppliers or other third parties with which we have business relationships, or governments may take in respect of the COVID-19 pandemic, could disrupt, delay, or otherwise adversely impact our business.

We are still assessing our business plans and the impact the COVID-19 pandemic may have on our ability to advance the testing, development and manufacturing of our drug candidates, including as a result of adverse impacts on the research sites, service providers, vendors, or suppliers on whom we rely, or to raise financing to support the development of our drug candidates. No assurances can be given that this analysis will enable us to avoid part or all of any impact from the spread of COVID-19 or its consequences, including downturns in business sentiment generally or in our sector in particular. We cannot presently predict the scope and severity 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

On September 17, 2018, we entered into a Series A2 Preferred Stock Purchase Agreement, or the Series A2 Agreement, with ElevateBio. ElevateBio was formed in November 2017 and is headquartered in Cambridge, Massachusetts, with a focus on the development of a portfolio of novel cell therapy programs acquired through business development activities with biotechnology companies. ElevateBio is structured as a holding company, comprised of asset-specific subsidiaries focused on the development of the pipeline assets, as well as a manufacturing subsidiary with the expertise to provide 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, ElevateBio acquired an ownership interest to our audited consolidated financial statements appearing elsewhere in this Form 10-K). The Chief Executive Officer, Chief Financial Officer, and other executives of ElevateBio also serve in similar management roles with us.

Initial Public Offering

On August 3, 2020, the Company completed its IPO, in which the Company issued and sold 18,687,500 shares of its common stock, at a public offering price of \$17.00 per share, resulting in gross proceeds of \$317.7 million. The Company received \$292.0 million in net proceeds after deducting underwriting discounts and commissions and offering costs. Upon the closing of the IPO, all of the then-outstanding shares of convertible preferred stock automatically converted into 39,859,139 shares of common stock at the applicable conversion ratio then in effect.

Reverse Stock Split

On July 22, 2020, the Company effected a 1-for-1.49020520953831 reverse stock split of the Company's common stock and adjusted the ratio at which the Company's preferred stock is convertible into common stock, as well as the number of shares under the 2018 Equity Incentive Plan and the Company's Amended and Restated Certificate of Incorporation, as well as the share amounts of restricted stock grants under the plan and the number of options and exercise prices of options under the plan as a result of the 1-for-1.49020520953831 reverse stock split. All common shares, stock options, and per share information presented in the accompanying consolidated financial statements and notes thereto have been adjusted, where applicable, to reflect the reverse stock split on a retroactive basis for all periods presented. The per share par value and authorized number of shares of the Company's common stock were not adjusted as a result of the split.

Components of Results of Operations

Revenue

All of our revenue has been derived from our grant agreement with the Cancer Research and Prevention Institute of Texas, or CPRIT. In November 2019, we provided CPRIT with written notice of our intent to terminate the grant, and received acknowledgment of the termination from CPRIT in January 2020. Notwithstanding such termination, our obligation to pay royalties to CPRIT will continue until such time as the Company's commercial products no longer maintain exclusivity or, if the Company's commercial products do not obtain exclusivity, 12 years after the first sale of the Company's commercial products. To date, we have not generated any revenue from product sales. If our development efforts for our product candidates and preclinical programs are successful and result in regulatory approval, we may generate revenue in the future from product sales.

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 contract research organizations, or 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 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 substantially 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, 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.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur significantly increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company.

Total Other Income, Net

Interest income

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

Other income, net

“Other income, net” consists primarily of investment amortization and accretion of discounts on short-term investments, other income from government grants based on expenditures that qualify for reimbursement and interest expense. Interest expense in 2019 related to a one-time charge from the termination of the CPRIT grant agreement on the unused portion of funds returned to CPRIT.

Results of Operations

Comparison of the Years Ended December 31, 2020 and 2019

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

	Years Ended December 31,		
	2020	2019	Change
Revenue	\$ —	\$ 165	\$ (165)
Operating expenses:			
Research and development	49,663	16,248	33,415
General and administrative	21,646	10,618	11,028
Total operating expenses	71,309	26,866	44,443
Loss from operations	(71,309)	(26,701)	(44,608)
Total other income, net:			
Interest income	1,330	2,065	(735)
Other income, net	195	797	(602)
Net loss	\$ (69,784)	\$ (23,839)	\$ (45,945)

Revenue

We recognized no revenue for the year ended December 31, 2020, while we recognized revenue of \$0.2 million for the year ended December 31, 2019 under the CPRIT grant. No revenue was recognized for the year ended December 31, 2020 as a result of the termination of the CPRIT grant in January 2020.

Research and Development Expenses

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

	Years Ended December 31,		Change
	2020	2019	
Direct research and development expenses by program:			
Viraly-M	\$ 20,384	\$ 6,497	\$ 13,887
ALVR106	5,206	1,202	4,004
ALVR109	753	—	753
Discovery	583	781	(198)
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	20,723	7,132	13,591
Other expenses	2,014	636	1,378
Total research and development expenses	\$ 49,663	\$ 16,248	\$ 33,415

Research and development expenses were \$49.7 million for the year ended December 31, 2020, compared to \$16.2 million for the year ended December 31, 2019. The increase of \$33.4 million was primarily due to:

- a \$13.9 million increase in costs related to the development of Viraly-M, our most advanced product candidate, primarily due to an increase in costs related to the outsourcing of manufacturing of \$5.8 million and the development of clinical trials of \$8.1 million;
- a \$4.0 million increase in costs related to the development of ALVR106, primarily due to an increase in costs related to the outsourcing of manufacturing of \$2.2 million and the development of clinical trials of \$1.8 million;
- a \$0.8 million increase in costs related to the development of ALVR109, primarily due to increased costs related to COVID-19 clinical trials;
- a \$0.2 million decrease in costs related to discovery activities as a result of decreased license fees;
- a \$13.6 million increase in personnel-related costs, including stock-based compensation expense, primarily due to an increase in employee headcount of \$7.9 million and the cost of external consultants in support of research activities of \$5.7 million; and
- a \$1.4 million increase in other research and development expenses, including facilities, rent, travel and equipment driven by an increase in headcount.

General and Administrative Expenses

General and administrative expenses were \$21.6 million for the year ended December 31, 2020, compared to \$10.6 million for the year ended December 31, 2019. The increase of \$11.0 million consisted of an increase of \$5.6 million in payroll and personnel-related costs, including stock-based compensation, primarily due to an increase in headcount, a \$3.1 million increase in professional and consulting fees for legal and accounting, a \$2.0 million increase in insurance and a \$0.3 million increase in software and IT services related to increased operations.

Total Other Income, Net

Total “other income, net” was \$1.5 million for the year ended December 31, 2020, compared to \$2.9 million for year ended December 31, 2019. The decrease of \$1.4 million is primarily attributable to a decrease of \$1.2 million resulting from a change in amortization and accretion of discounts on short-term investments.

Liquidity and Capital Resources

Sources of Liquidity

At December 31, 2020, 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 and \$292.0 million of net proceeds from the sale of common stock in our IPO.

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

Funding Requirements

At December 31, 2020, our cash, cash equivalents and short-term investments were \$356.3 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 into 2023. 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 activities. In addition, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. If we receive regulatory approval for our other 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 Viralym-M for our initial and potential additional indications, as well as ALVR106, ALVR109 and other product candidates we may develop, including any COVID-19-related delays or other effects on our development programs;
- the timing of, and the costs involved in, obtaining marketing approvals for Viralym-M 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 Viralym-M 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 Viralym-M 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.

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):

	Years Ended December 31,	
	2020	2019
Net cash used in operating activities	\$ (60,811)	\$ (20,155)
Net cash used in investing activities	(169,497)	(64,644)
Net cash provided by financing activities	291,975	120,923
Effect of exchange rate changes on cash and cash equivalents	(90)	—
Net increase in cash and cash equivalents	<u>\$ 61,577</u>	<u>\$ 36,124</u>

Operating Activities

Net cash used in operating activities was \$60.8 million for the year ended December 31, 2020, reflecting a net loss of \$69.8 million, partially offset by non-cash charges of \$10.0 million. The non-cash charges primarily consist of depreciation and amortization, amortization of discounts on short-term investments and stock compensation expense. The change in our net operating assets and liabilities of \$1.0 million was primarily due to an increase of \$4.0 million in prepaid expenses and other current assets and accrued interest, partially offset by an increase of \$2.7 million in accounts payable, accrued expenses and amount due to related party and a decrease of \$0.3 million in unbilled grants receivable.

Net cash used in operating activities was \$20.2 million for the year ended December 31, 2019, reflecting a net loss of \$23.8 million, offset by a net change of \$1.4 million in our net operating assets and non-cash charges of \$2.3 million. The non-cash charges primarily consist of depreciation and amortization, accretion of investment discounts and stock compensation expense. The change in our net operating assets and liabilities was primarily due to an increase of \$4.9 million in accounts payable and accrued expenses, partially offset by a decrease of \$2.7 million in deferred grant revenue, an increase of \$0.3 million in accrued interest and an increase of \$0.6 million in prepaid expenses and other current assets.

The \$40.6 million increase in cash used in operating activities for the year ended December 31, 2020 compared to the year ended December 31, 2019 is primarily due to an increase in research and development expenses and general and administrative expenses as a result of advancing the development of Viralym-M, ALVR106 and ALVR109 and operating as a public company, including increased personnel costs related to our increased headcount and our increased efforts towards identifying product candidates.

Investing Activities

Net cash used in investing activities was \$169.5 million for the year ended December 31, 2020. Cash used in investing activities for the year ended December 31, 2020 was primarily due to the purchase of investments of \$300.3 million and the purchase of property and equipment of \$0.2 million, partially offset by investment maturities of \$131.0 million.

Net cash used in investing activities was \$64.6 million for the year ended December 31, 2019. Net cash used in investing activities for the year ended December 31, 2019 was primarily due to the purchase of investments of \$119.3 million, partially offset by investment maturities of \$55.0 million.

Financing Activities

Net cash provided by financing activities was \$292.0 million for the year ended December 31, 2020 due to proceeds from our IPO, net of issuance costs paid.

Net cash provided by financing activities was \$120.9 million for the year ended December 31, 2019 consisting of net proceeds from the issuance of Series B Preferred Stock in May 2019.

Contractual Obligations

The following table summarizes our contractual obligations at December 31, 2020 (in thousands):

	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Purchase obligations	\$ 8,001	\$ 3,048	\$ 4,953	\$ —	\$ —
Collaboration commitments	5,989	2,000	3,989		
Operating lease obligations	11,700	5,100	6,600	—	—
Total	<u><u>\$ 25,690</u></u>	<u><u>\$ 10,148</u></u>	<u><u>\$ 15,542</u></u>	<u><u>\$ —</u></u>	<u><u>\$ —</u></u>

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions and the approximate timing of the actions under the contracts.

Operating Lease

Operating lease payments represent our commitments for future minimum rent made under non-cancelable leases for manufacturing suites. This amount includes all manufacturing suite lease agreements signed at December 31, 2020, including the one with ElevateBio BaseCamp, Inc., of which has not yet commenced. For additional details regarding our leases, see Note 5. *Leases* to our consolidated financial statements.

Sponsored Research and Collaboration Agreements

In June 2019, we entered into a sponsored research agreement, or SRA-2, with Baylor College of Medicine, or BCM, under which we agreed to pay BCM for performing certain research activities related to virus-specific T-cell manufacturing for a one-year period, renewable for an additional one-year term upon written consent of both parties. SRA-2 requires us to make payments to BCM totaling \$1.0 million, payable in four equal installments. SRA-2 was amended in March 2020 to include new technology, pre-clinical therapies and related patent rights related to a number of new viruses, including SARS-CoV-2 as well as an additional technology developed by BCM under SRA-2 since the original agreement was executed. In June 2020, a second amendment was entered into resulting in a no-cost extension through November 30, 2020, upon which the agreement terminated.

In November 2020, the Company also entered into a Research Collaboration Agreement (the “Research Agreement”) with BCM, effective on the same date, under which the Company agreed to pay BCM for performing certain research activities under the direction of Dr. Ann Leen commencing on January 1, 2021 and continuing for a three-year period thereafter. The Research Agreement requires the Company to make payments to BCM totaling approximately \$2.0 million per year, for a total of approximately \$6.0 million over the term of the Research Agreement. These payments are included in the table above.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs and other third-party vendors for clinical trials and testing and manufacturing services. Aside from those included in the table above, most contracts do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation consist of payments for services provided or expenses incurred, including non-cancelable obligations of our service provided up to one year after the date of cancellation. These payments are not included in the table above as the amount and timing of such payments are not known.

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel and with vendors to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period.

Stock-Based Compensation Expense

We grant restricted stock and stock options to employees, consultants, and directors. We measure stock-based compensation based on the grant date fair value of the stock-based awards, and recognize stock-based compensation cost for awards with performance conditions if and when we conclude that it is probable that the performance conditions will be achieved using a graded-vesting basis over the requisite employee service period. For awards with only a service condition, we expense stock-based compensation on a straight-line basis over the requisite employee service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as they occur. On January 1, 2019, we adopted the guidance of Accounting Standards Update (ASU) No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Non-employee Share-based Payment Accounting* (ASU 2018-07), and account for awards to non-employees using the grant date fair value without subsequent periodic remeasurement. The adoption of ASU 2018-07 did not have a material effect on our consolidated financial statements.

Stock-based compensation expense is classified in our consolidated statements of operations and comprehensive loss based on the function to which the related services are provided or in the same manner in which the grantee's payroll costs are classified or in which the grantee's service payments are classified.

Prior to our IPO, we estimated the fair value of each stock option grant and restricted common stock award. We consider the fair value of our common stock, an input to the option pricing models, a critical accounting estimate.

Valuation of Common Stock

The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the fair value of our common stock and assumptions we make for the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option and our expected dividend yield.

The expected term of our options granted to employees has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. With the adoption of ASU 2018-07, we applied the practical expedient for calculating the expected term of non-employee awards, using the midpoint between the vesting date and the contractual term, which is consistent with the method used for employee awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. We have not paid, and do not anticipate paying, dividends on our common stock; therefore, the expected dividend yield is assumed to be zero.

Prior to our IPO, the fair value of each restricted common stock award was estimated on the date of grant based on the fair value of our common stock on that same date. In estimating its stock price, the Company utilized a hybrid method consisting of an option-pricing method and a zero-value scenario. We determine the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted-average of the historical volatility measures of this group of guideline companies. We expect to continue to do so until we have adequate historical data regarding the volatility of the trading price of our common stock on Nasdaq.

As there had been no public market for our common stock prior to the initial public offering of our common stock, the historical estimated fair value of our common stock has been approved by our board of directors, considering our most recently available independent third-party valuations of common stock. In accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*, a third-party valuation firm prepared valuations of our common stock using either an option pricing method, or OPM, or a hybrid method, both of which used market approaches to estimate our enterprise value.

In addition to considering the results of the third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of our common stock as of each grant date, which may be a date later than the most recent third-party valuation date, including:

- the prices at which we sold preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development efforts, including the status of clinical studies for our product candidates;
- the lack of liquidity of our equity as a private company;
- our stage of development and business strategy and the material risks related to our business and industry;
- the achievement of enterprise milestones, including entering into collaboration and license agreements;
- the valuation of publicly traded companies in the life sciences and biotechnology sectors, as well as recently completed mergers and acquisitions of peer companies;
- any external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the likelihood of achieving a liquidity event for the holders of our preferred stock and holders of our common stock, such as an IPO, or a sale of our company, given prevailing market conditions; and
- the analysis of IPOs and the market performance of similar companies in the biopharmaceutical industry.

There are significant judgments and estimates inherent in these valuations. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation expense could be materially different.

Following the closing of our initial public offering, the fair value of our common stock is determined based on the quoted market price of our common stock.

Emerging Growth Company Status

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. The JOBS Act provides that, among other things, an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. As an emerging growth company, we have irrevocably elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth public companies on a case-by-case basis. As a result, our consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

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

We will remain an emerging growth company until the earlier to occur of (1) the last day of our fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenues of at least \$1.0 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.

Off-Balance Sheet Arrangements

At December 31, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

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 consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

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

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.**Evaluation of Disclosure Controls and Procedures**

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

Our management, with the participation of our Chief Executive Officer and our Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2020. Based on the evaluation of our disclosure controls and procedures as of December 31, 2020, our Chief Executive Officer and our Chief Financial Officers concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

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

This report does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies.

As a result of the COVID-19 pandemic, certain employees began working remotely in March 2020. Notwithstanding these changes to the working environment, we have not identified any material changes in our internal control over financial reporting. We will continue to monitor and assess the COVID-19 situation to determine any potential impact on the design and operating effectiveness of our internal controls over financial reporting.

Inherent Limitations on Effectiveness of Controls

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

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of the Stockholders and is included herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of the Stockholders and is included herein by reference.

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

The information required by this Item 12 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of the Stockholders and is included herein by reference.

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

The information required by this Item 13 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of the Stockholders and is included herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our definitive proxy statement to be filed with the SEC with respect to our 2021 Annual Meeting of the Stockholders and is included herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(1) Consolidated Financial Statements

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

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

(2) Financial Statement Schedules

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

(3) Exhibits

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

Exhibit Index

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
3.2	Second Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.5 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
4.1	Amended and Restated Investors' Rights Agreement among the Registrant and certain of its stockholders, effective as of May 8, 2019 (incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
4.2*	Description of the Registrant's securities registered pursuant to Section 12 of the Securities and Exchange Act of 1934, as amended.
10.1#	2018 Equity Incentive Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.2#	2020 Stock Option and Grant Plan, and form of award agreements thereunder (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
10.3#	2020 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).
10.4#	Form of Indemnification Agreement between the Registrant and each of its directors (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.5#	Form of Indemnification Agreement between the Registrant and each of its executive officers (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.6	Lease Agreement between the Registrant and Regus Management Group, LLC, dated as of January 3, 2019, as amended by the Renewal Agreement, entered into on December 10, 2019 (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-23969) filed on July 6, 2020).
10.7†	Amended and Restated Exclusive License Agreement, by and between Baylor College of Medicine and the Registrant, dated as of May 11, 2020 (incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1/A (File No. 333-239698) filed on July 23, 2020).

- 10.8† [Sponsored Research Agreement, by and between Baylor College of Medicine and the Registrant, dated as of June 18, 2019, as amended by the Amendment to Sponsored Research Agreement, entered into on April 7, 2020 \(incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1/A \(File No. 333-239698\) filed on July 23, 2020\).](#)
- 10.9 [Asset Rental Agreement, by and between ElevateBio Management, Inc. and the Registrant, dated as of May 1, 2019 \(incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 \(File No. 333-23969\) filed on July 6, 2020\).](#)
- 10.10 [Sublease Agreement, by and between ElevateBio Management, Inc. and the Registrant, dated as of May 1, 2019 \(incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 \(File No. 333-23969\) filed on July 6, 2020\).](#)
- 10.11# [Consulting Agreement, by and between Juan Vera and the Registrant, dated as of October 1, 2018 \(incorporated by reference to Exhibit 10.11 of the Registrant's Registration Statement on Form S-1 \(File No. 333-23969\) filed on July 6, 2020\).](#)
- 10.12# [Consulting Agreement, by and between Ann Leen and the Registrant, dated as of October 1, 2018 \(incorporated by reference to Exhibit 10.12 of the Registrant's Registration Statement on Form S-1 \(File No. 333-23969\) filed on July 6, 2020\).](#)
- 10.13† [Redeemable Preferred Stock Redemption Agreement among the Registrant and certain of its stockholders, effective as of September 17, 2018 \(incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1/A \(File No. 333-239698\) filed on July 23, 2020\).](#)
- 10.14# [Amended and Restated Executive Employment Agreement, by and between the Registrant and David Hallal, dated as of October 2, 2019 \(incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1/A \(File No. 333-239698\) filed on July 23, 2020\).](#)
- 10.15# [Amended and Restated Executive Employment Agreement, by and between the Registrant and Vikas Sinha, dated as of October 2, 2019 \(incorporated by reference to Exhibit 10.15 of the Registrant's Registration Statement on Form S-1/A \(File No. 333-239698\) filed on July 23, 2020\).](#)
- 10.16# [Executive Employment Agreement, by and between the Registrant and Agustin Melian, dated as of March 21, 2019 \(incorporated by reference to Exhibit 10.16 of the Registrant's Registration Statement on Form S-1/A \(File No. 333-239698\) filed on July 23, 2020\).](#)
- 10.17#* [Executive Employment Agreement, by and between the Registrant and Ercem Atillasoy, dated as of July 14, 2020.](#)
- 10.18†* [Exclusive License Agreement, by and between Baylor College of Medicine and the Registrant, dated as of November 30, 2020.](#)
- 10.19†* [Research Collaboration Agreement, by and between Baylor College of Medicine and the Registrant, dated as of November 30, 2020.](#)
- 10.20†* [First Amendment to Amended and Restated Exclusive License Agreement by and between Baylor College of Medicine and the Registrant, dated as of November 30, 2020.](#)
- 21.1 [List of Subsidiaries of Registrant \(incorporated by reference to Exhibit 21.1 of the Registrant's Registration Statement on Form S-1 \(File No. 333-23969\) filed on July 6, 2020\).](#)
- 23.1* [Consent of Deloitte & Touche LLP, independent registered public accounting firm.](#)
- 24.1* [Power of Attorney \(included on signature page\).](#)
- 31.1* [Certification of Principal Executive Officer Pursuant to Rules 13a-14\(a\) and 15d-14\(a\) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 31.2* [Certification of Principal Financial Officer Pursuant to Rules 13a-14\(a\) and 15d-14\(a\) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.](#)
- 32.1* [Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)
- 32.2* [Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.](#)

101.INS XBRL Instance Document
101.SCH XBRL Taxonomy Extension Schema Document
101.CAL XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF XBRL Taxonomy Extension Definition Linkbase Document
101.LAB XBRL Taxonomy Extension Label Linkbase Document
101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

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

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

16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

ALLOVIR, INC.

Date: February 12, 2021

By: _____ /s/ David Hallal
David Hallal
Chief Executive Officer and Director
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose individual signature appears below hereby authorizes and appoints David Hallal with full power of substitution and resubstitution and full power to act as his or her true and lawful attorney-in-fact and agent to act in his or her name, place and stead and to execute in the name and on behalf of each person, individually and in each capacity stated below, and to file any and all amendments to this Annual Report on Form 10-K and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing, ratifying and confirming all that said attorney-in-fact and agent or his substitute or substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Signature	Title	Date
/s/ David Hallal David Hallal	Chief Executive Officer and Director <i>(Principal Executive Officer)</i>	February 12, 2021
/s/ Vikas Sinha Vikas Sinha	President, Chief Financial Officer and Director <i>(Principal Financial Officer and Principal Accounting Officer)</i>	February 12, 2021
/s/ Jeffrey Bornstein Jeffrey Bornstein	Director	February 12, 2021
/s/ Diana M. Brainard, MD Diana M. Brainard, MD	Director	February 12, 2021
/s/ John Wilson John Wilson	Director	February 12, 2021
/s/ Ansbert Gadicke, MD Ansbert Gadicke, MD	Director	February 12, 2021
/s/ Morana Jovan-Embiricos, PhD Morana Jovan-Embiricos, PhD	Director	February 12, 2021
/s/ Malcolm Brenner, MD, PhD Malcolm Brenner, MD, PhD	Director	February 12, 2021
/s/ Juan F. Vera, MD Juan F. Vera, MD	Director	February 12, 2021

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Consolidated Financial Statements for the Years Ended December 31, 2020 and 2019:

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets</u>	F-3
<u>Consolidated Statements of Operations and Comprehensive Loss</u>	F-4
<u>Consolidated Statements of Convertible Preferred Stock and Changes in Stockholders' Equity (Deficit)</u>	F-5
<u>Consolidated Statements of Cash Flows</u>	F-6
<u>Notes to Consolidated Financial Statements</u>	F-7

F-1

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of AlloVir, Inc. (formerly ViraCyte, Inc.) and subsidiaries (the “Company”) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, convertible preferred stock and changes in stockholders’ equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2020, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

February 12, 2021

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

ALLOVIR, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2020	2019
(in thousands, except share and per share amounts)		
Assets		
Current assets:		
Cash and cash equivalents	\$ 122,661	\$ 61,084
Short-term investments	233,663	64,993
Accrued interest	450	262
Unbilled grant receivables	—	298
Prepaid expenses and other current assets	4,543	676
Total current assets	361,317	127,313
Property and equipment, net	812	350
Operating lease right-of-use assets	8,692	11,759
Total assets	\$ 370,821	\$ 139,422
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 963	\$ 630
Accrued expenses	7,530	5,163
Operating lease liability, current	3,229	3,067
Amount due to related party	572	246
Total current liabilities	12,294	9,106
Operating lease liability, long term	5,463	8,692
Total liabilities	17,757	17,798
Series B preferred stock, \$0.0001 par value: 0 and 14,877,697 shares authorized, issued and outstanding at December 31, 2020 and 2019, respectively	—	120,923
Series A preferred stock, \$0.0001 par value: 0 and 64,520,653 shares authorized at December 31, 2020 and 2019, respectively; 0 and 44,520,653 shares issued and outstanding at December 31, 2020 and 2019, respectively	—	52,204
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value: 10,000,000 and 0 shares authorized at December 31, 2020 and 2019, respectively; 0 shares issued and outstanding at December 31, 2020 and 2019, respectively;	—	—
Common stock, \$0.0001 par value: 150,000,000 and 90,000,000 shares authorized at December 31, 2020 and 2019, respectively; 65,106,873 and 6,502,929 shares issued at December 31, 2020 and 2019, respectively; and 61,931,255 and 2,099,740 shares outstanding at December 31, 2020 and 2019, respectively	7	—
Additional paid-in capital	478,272	3,748
Accumulated other comprehensive (loss) income	(112)	68
Accumulated deficit	(125,103)	(55,319)
Total stockholders' equity (deficit)	353,064	(51,503)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 370,821	\$ 139,422

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

ALLOVIR, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years Ended December 31,	
	2020	2019
(in thousands, except share and per share amounts)		
Revenue	\$ —	\$ 165
Operating expenses:		
Research and development	49,663	16,248
General and administrative	21,646	10,618
Total operating expenses	71,309	26,866
Loss from operations	(71,309)	(26,701)
Total other income, net:		
Interest income	1,330	2,065
Other income, net	195	797
Net loss	(69,784)	(23,839)
Net loss per share – basic and diluted	\$ (2.59)	\$ (18.54)
Weighted-average common shares outstanding – basic and diluted	26,897,390	1,285,933
Comprehensive loss:		
Net loss	\$ (69,784)	\$ (23,839)
Other comprehensive (loss) income, net of tax:		
Unrealized (loss) gain on available-for-sale securities	(90)	68
Foreign currency translation adjustment	(90)	—
Total other comprehensive (loss) income	(180)	68
Comprehensive loss	\$ (69,964)	\$ (23,771)

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

ALLOVIR, INC.
CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND CHANGES IN STOCKHOLDERS' EQUITY
(DEFICIT)

(in thousands, except share amounts)	Series B Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	(Loss) Income	Deficit	(Deficit)
Balance at December 31, 2018	—	\$ —	42,066,666	\$ 52,204	747,231	\$ —	\$ 858	\$ 0	\$ (31,480)	\$ (30,622)
Issuance of Series B Preferred Stock, net of \$330 issuance costs	14,877,697	\$ 120,923								
Conversion of all Series A1 Preferred Stock to Series A3 Preferred Stock and issuance of additional shares of Series A3 Preferred Stock			2,453,987	—						
Stock-based compensation	—	—	—	—			2,890			2,890
Issuance of common stock, upon vesting of restricted stock	—	—	—	—	1,352,509	—	—			
Unrealized gain on available-for- sale securities	—	—	—	—				68	—	68
Net loss	—	—	—	—	—	—	—	—	(23,839)	(23,839)
Balance at December 31, 2019	14,877,697	\$ 120,923	44,520,653	\$ 52,204	2,099,740	\$ —	\$ 3,748	\$ 68	\$ (55,319)	\$ (51,503)
Initial public offering, net of underwriting discounts, commissions, and offering costs	—	—	—	—	18,687,500	2	291,973	—	—	291,975
Conversion of convertible	(14,877,697)	(120,923)	(44,520,653)	(52,204)	39,859,139	5	173,122	—	—	173,127

preferred stock into common stock upon initial public offering								
Stock-based compensation	—	—	—	—	—	9,429	—	—
Issuance of common stock, upon vesting of restricted stock	—	—	—	—	1,284,876	—	—	—
Unrealized loss on available-for- sale securities	—	—	—	—	—	(90)	—	(90)
Foreign currency translation adjustment	—	—	—	—	—	(90)	—	(90)
Net loss	—	—	—	—	—	—	(69,784)	(69,784)
Balance at December 31, 2020	—	\$	—	—	61,931,255	\$	7	\$478,272
							\$ (112)	\$ (125,103)
								\$ 353,064

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

ALLOVIR, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands, except share and per share amounts)	Years Ended December 31,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (69,784)	\$ (23,839)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	73	19
Amortization and accretion of discounts on short-term investments	502	(620)
Stock compensation expense	9,429	2,890
Changes in operating assets and liabilities:		
Unbilled grant receivables	298	4
Accrued interest	(188)	(262)
Prepaid expenses and other current assets	(3,867)	(620)
Accounts payable, accrued expenses and amount due to related party	2,726	4,936
Deferred grant revenue	—	(2,663)
Net cash used in operating activities	(60,811)	(20,155)
Cash flows from investing activities		
Purchase of property and equipment	(235)	(339)
Purchase of short-term investments	(300,262)	(119,305)
Maturities of short-term investments	131,000	55,000
Net cash used in investing activities	(169,497)	(64,644)
Cash flows from financing activities		
Proceeds from issuance of Series B Preferred Stock	—	121,253
Issuance costs related to the issuance of preferred stock	—	(330)
Payment of initial public offering costs	(3,474)	—
Proceeds from issuance of common stock upon initial public offering, net of underwriting discounts of \$22,238	295,449	—
Net cash provided by financing activities	291,975	120,923
Effect of exchange rate changes on cash and cash equivalents	(90)	—
Net increase in cash and cash equivalents	61,577	36,124
Cash and cash equivalents at beginning of period	61,084	24,960
Cash and cash equivalents at end of period	\$ 122,661	\$ 61,084
Non-cash investing and financing activities		
Unrealized (loss) gain on available-for-sale securities	\$ (90)	\$ 68
Right-of-use assets obtained in exchange for operating lease liability	\$ —	\$ 13,213
Purchase of property and equipment included in AP and accrued expenses	\$ 300	\$ 30
Issuance of Series A3 Preferred Stock related to anti-dilution rights	\$ —	\$ 3,681
Conversion of preferred stock to common stock upon initial public offering	\$ 173,127	—
Supplemental disclosure of cash flows		
Cash paid for interest	\$ —	\$ 125

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

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business

AlloVir, Inc. (“AlloVir” or “the Company”, formerly known as ViraCyte, Inc.) is a 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. To date, the Company has generated five innovative, allogeneic, off-the-shelf VST therapy candidates targeting 12 different devastating viruses, the most advanced for which the Company has initiated a pivotal trial for the treatment of virus-associated hemorrhagic cystitis and a proof-of-concept, or POC, clinical trial for multi-virus prevention in the fourth quarter of 2020.

The Company’s lead product candidate, Viralym-M, is a multi-VST cell therapy that targets five viruses: BK virus, cytomegalovirus, adenovirus, Epstein-Barr virus and human herpesvirus 6. To fully explore the clinical benefit of Viralym-M, the Company plans to initiate a total of three Phase 3 pivotal and three Phase 2 proof-of-concept trials by the end of 2021 for the treatment and prevention of life-threatening viral diseases in pediatric and/or adult patients, each representing a potential meaningful commercial opportunity. In addition, ALVR106 is the Company’s second multi-virus-targeted off-the-shelf VST product candidate targeting devastating respiratory diseases caused by RSV, influenza, PIV and/or hMPV. An Investigational New Drug, or IND, application with the FDA for ALVR106 was cleared in the fourth quarter of 2020 and the Company plans to initiate a Phase 1/2 clinical study in autologous and allogeneic HSCT patients with respiratory viral diseases in the 2021-2022 respiratory virus season. Pursuant to the sponsored research agreement with Baylor College of Medicine (“BCM”), BCM initiated a proof-of-concept trial for ALVR109, an allogeneic, off-the-shelf VST therapy designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19. ALVR109 is being developed to arrest the progression of COVID-19 by eradicating SARS-CoV-2 virus-infected cells. BCM initiated the POC clinical trial in the fourth quarter of 2020 and the trial is ongoing and actively recruiting. Lastly, the Company is advancing ALVR107 designed to target hepatitis B, or HBV, infected cells and treat chronic HBV infections and ALVR108 to treat human herpesvirus-8, or HHV-8, associated diseases including Kaposi Sarcoma, or KS, primary effusion lymphoma, or PEL, and multicentric Castleman’s disease, or MCD. The Company plans to complete pre-clinical IND enabling studies for ALVR107 and ALVR108 in the second half of 2021.

The Company was formed on August 16, 2013 as a Delaware limited liability company (“LLC”) under the name AdCyte LLC and on July 29, 2014 the Company changed its name to ViraCyte LLC. On September 17, 2018, the Company converted from a Delaware LLC to a Delaware corporation (“LLC Conversion”) and changed its name to ViraCyte, Inc. On May 22, 2019, the Company changed its name to AlloVir, Inc. The Company has principal offices in Houston, Texas and Cambridge, Massachusetts.

On August 8, 2019, AlloVir formed AlloVir International Designated Activity Company (“AlloVir International”), a wholly-owned subsidiary established in Ireland.

On October 9, 2019, AlloVir Securities Corporation was incorporated as a Massachusetts Security Corporation, a wholly-owned subsidiary of AlloVir.

On November 10, 2019, AlloVir International formed AlloVir Italia S.R.L. (“AlloVir Italia”), a wholly-owned subsidiary in Italy.

On August 3, 2020, the Company completed an initial public offering (“IPO”) in which the Company issued and sold 18,687,500 shares of its common stock, at a public offering price of \$17.00 per share, resulting in gross proceeds of \$317.7 million. The Company received \$292.0 million in net proceeds after deducting underwriting discounts and commissions and offering costs.

Upon the closing of the IPO, all of the then-outstanding shares of convertible preferred stock automatically converted into 39,859,139 shares of common stock at the applicable conversion ratio then in effect. Subsequent to the closing of the IPO, there were no shares of convertible preferred stock outstanding.

ElevateBio LLC

On September 17, 2018, the Company executed a Series A2 Preferred Stock Purchase Agreement (“Series A2 Agreement”) with ElevateBio, LLC, a Delaware LLC (“ElevateBio”) concurrent with the LLC Conversion. ElevateBio was formed on November 29, 2017 and is headquartered in Cambridge, Massachusetts with a focus on the development of a portfolio of novel cell therapy programs acquired through business development activities with biotechnology companies. ElevateBio is structured as a holding company, comprised of asset-specific subsidiaries focused on the development of pipeline assets, as well as a manufacturing subsidiary with the expertise to provide drug development and manufacturing services. As a result of the purchase of the Company’s Series A2 Preferred Stock, ElevateBio acquired an ownership interest in the Company (see Note 17 for further discussion). The Chief Executive Officer, Chief Financial Officer, and other executives of ElevateBio also serve in similar management roles with AlloVir.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Going Concern

In accordance with Accounting Standards Update (“ASU”) 2014-15, *Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (Subtopic 205-40)*, the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date the consolidated financial statements are issued.

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 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 December 31, 2020, 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 \$69.8 million for the year ended December 31, 2020 and \$23.8 million for the year ended December 31, 2019. In addition, at December 31, 2020, the Company had an accumulated deficit of \$125.1 million. The Company expects to continue to generate operating losses for the foreseeable future.

The Company believes that its \$122.7 million of cash and cash equivalents and \$233.7 million of short-term investments held at December 31, 2020, are sufficient to fund planned operations for at least twelve months from the date that these consolidated financial statements are available to be issued.

The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business.

COVID-19 Considerations

The development of 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 recent COVID-19 pandemic. The spread of COVID-19 has impacted the global economy and has impacted 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. If the disruption due to the COVID-19 pandemic continues, planned pivotal clinical trials also could be delayed due to government orders and site policies on account of the pandemic, and some patients may be unwilling or unable to travel to study sites, enroll in trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay the Company’s ability to conduct preclinical studies and clinical trials or release clinical trial results and could delay the Company’s ability to obtain regulatory approval and commercialize product candidates. Furthermore, COVID-19 could affect the Company’s employees or the employees of research sites and service providers on whom the Company relies on as well as those of companies with which the Company does business, including suppliers and contract manufacturing organizations or CMOs, thereby disrupting business operations. Quarantines and travel restrictions imposed by governments in the jurisdictions in which the Company and the companies with which it does business operate could materially impact the ability of employees to access preclinical and clinical sites, laboratories, manufacturing sites and offices. The Company has implemented work-at-home policies and only employees essential to the development and research of product candidates remain on-site at the Company’s research and manufacturing facilities; accordingly, the Company may experience limitations in employee resources. The outbreak and any other preventative or protective actions that the Company, its suppliers or other third parties with which it has business relationships, or governments may take in respect of the COVID-19 pandemic, could disrupt, delay or otherwise adversely impact the business.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company is still assessing business plans and the impact the COVID-19 pandemic 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 and severity 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

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP"). The consolidated financial statements include the Company's accounts and those of its wholly-owned subsidiaries. All intercompany accounts, transactions and balances have been eliminated in consolidation.

Segment Information

Operating segments are defined as components of an enterprise for which separate and discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company has one operating segment. The Company's singular focus is the research, development and commercialization of off-the-shelf VST therapies to prevent and treat severe viral-associated diseases. The Company's chief operating decision maker, its Chief Executive Officer, manages the Company's operations on a consolidated basis for the purpose of allocating resources. All of the Company's long-lived assets are held in the United States.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Changes in estimates and assumptions are reflected in reported results in the period in which they become known. Actual results could differ from those estimates.

Cash and Cash Equivalents

Cash and cash equivalents are short-term, highly liquid investments with original maturities of three months or less at the date of purchase. Investments qualifying as cash equivalents primarily consist of money market funds and demand deposits.

Short-Term Investments

Short-term investments consist of U.S. treasury securities classified as available-for-sale that have maturities of less than one year. Available-for-sale securities are carried at fair value, with the unrealized gains and losses reported in other comprehensive income. The amortized cost of debt securities in this category is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization or accretion is included in interest income.

The cost of securities sold is based on the specific identification method. Interest on debt securities classified as available-for-sale are included in interest income. To determine whether an other-than-temporary impairment exists, the Company considers whether it has the ability and intent to hold the investment until a market price recovery, and whether evidence indicating the recoverability of the cost of the investment outweighs evidence to the contrary. There were no individual securities with impairments at December 31, 2020 and 2019.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Property and Equipment, Net

The Company records property and equipment at cost and recognizes depreciation using the straight-line method over the estimated useful lives of the respective assets. The Company holds laboratory equipment with a useful life of five years. The Company periodically evaluates whether events and circumstances have occurred that may warrant revision of the estimated useful life of property and equipment. Expenditures for repairs and maintenance of assets are expensed as incurred. Upon retirement or sale, the cost of assets disposed and the corresponding accumulated depreciation are removed from the related accounts and any resulting gain or loss is reflected in the results of operations. Construction in progress is not depreciated until it is placed in service. Property and equipment to be disposed of are carried at fair value less costs to sell.

Impairment of Long-Lived Assets

The Company accounts for long-lived assets in accordance with ASC Topic 360, *Property, Plant, and Equipment* (“ASC 360”). ASC 360 requires companies to: (i) recognize an impairment loss only if the carrying amount of a long-lived asset is not recoverable based on its undiscounted future cash flows and (ii) measure an impairment loss as the difference between the carrying amount and the fair value of the asset.

The Company tests long-lived assets to be held and used, including property and equipment, for impairment whenever events or changes in circumstances indicate that the carrying amount of assets or asset groups may not be fully recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the assets, the assets are written-down to their fair values. The Company has not recognized any impairment losses during the years ended December 31, 2020 and 2019.

Fair Value Measurements

ASC Topic 820, *Fair Value Measurement* (“ASC 820”), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company’s own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company’s assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances.

ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes among the following:

- Level 1 – Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.
- Level 2 – Valuations based on quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active and models for which all significant inputs are observable, either directly or indirectly.
- Level 3 – Valuations based on inputs that are unobservable and significant to the overall fair value measurement.

To the extent that the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument’s level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Financial instruments consist of cash and cash equivalents, short-term investments, unbilled grant receivable, accounts payable and accrued expenses. These financial instruments are stated at their respective historical carrying amounts, which approximate fair value due to their short-term nature.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are presented in the consolidated balance sheets as a direct reduction from the carrying amount of the respective equity instrument issued. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. Upon closing the IPO in August 2020, deferred offering costs were derecognized and recorded against the IPO proceeds as a debit to additional paid-in capital. At December 31, 2020 and 2019, the Company had recorded deferred offering costs of \$0 and \$0.1 million, respectively.

Revenue Recognition

The Company's sole source of revenue in 2019 was related to a grant ("CPRIT Grant") dated August 31, 2017 from the Cancer Research and Prevention Institute of Texas ("CPRIT").

The Company accounts for revenues under ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). The Company assesses each contract using the following approach and recognizes any revenue accordingly.

Under ASC 606, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the Company expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of ASC 606, the Company performs the following five steps: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations based on estimated standalone selling prices; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation. A performance obligation is a promise in a contract to transfer a distinct good or service to the customer.

The Company identifies the goods or services promised within each agreement and assesses whether each promised good or service is distinct for the purpose of identifying the performance obligations in the contract. This assessment involves subjective determinations and requires management to make judgments about the individual promised goods or services and whether such are separable from the other aspects of the contractual relationship. Promised goods and services are considered distinct provided that: (i) the customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer and (ii) the entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. If a promised good or service is not distinct, an entity is required to combine that promised good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

The allocation of the transaction price to the performance obligations in proportion to their standalone selling prices is determined at contract inception. If the consideration promised in a contract includes a variable amount, the Company estimates the amount of consideration to which it will be entitled in exchange for transferring the promised goods or services to a customer. The Company determines the amount of variable consideration by using the expected value method or the most likely amount method. The Company includes the unconstrained amount of estimated variable consideration in the transaction price. The amount included in the transaction price is the amount for which it is probable that a significant reversal of cumulative revenue recognized will not occur. At the end of each subsequent reporting period, the Company re-evaluates the estimated variable consideration included in the transaction price and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis in the period of adjustment.

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation as each performance obligation is satisfied. The Company concluded that the CPRIT Grant represents a contract with a customer and qualifies to be accounted for under ASC 606. In accordance with the grant, the performance obligations include performing a phase IIB clinical trial to establish the safety and effectiveness of Viralym-M in adults and children with a common, very severe virus infection (BK Virus) after stem cell transplant, and the granting of a non-commercial license to CPRIT.

The Company has concluded that the license and research and development services should be combined into a single performance obligation as they are highly interdependent.

Funds received are reflected in deferred revenue as a liability until revenue is earned. Grant revenue is recognized when qualifying costs are incurred (See Note 9 for further reference).

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Other Income, Net

The Company records interest expense, investment amortization and accretion and other government grants, not considered customers under ASC 606, in “other income, net” over the same period in which the qualifying costs are incurred. Proceeds received prior to the costs being incurred or the conditions of the award being met are recognized as deferred grant income until the services are performed and the conditions of the grant are met. To the extent that qualifying costs have been incurred prior to receipt of funds, the Company records an unbilled grant receivable upon recognition of those expenses.

Research and Development Costs

Research and development costs are charged to expense as incurred. Research and development expenses are comprised of costs incurred in performing research and development activities, including personnel-related costs, stock-based compensation, facilities, research-related overhead, clinical trial costs, contracted services, research-related manufacturing, license fees and other external costs. The Company accounts for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the services have been performed or when the goods have been received.

Accrued Research and Development Expenses

The Company has entered into various research and development contracts. The payments under these contracts are recorded as research and development expenses as incurred. The Company records accrued liabilities for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgements and estimates are made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company’s estimates. The Company’s historical accrual estimates have not been materially different from the actual costs.

Research and Development Grants

Grants are recognized as a receivable at their fair value when there is reasonable assurance that the grant will be received and the Company will comply with all the attached conditions. Grants receivable are recognized on a systematic basis as income over the periods necessary to match them with the related costs which they are intended to compensate. Grants that have been earned, other than those grants that fall under ASC 606, where the Company determined that the grantor is a customer, are presented in the consolidated statements of operations and comprehensive loss as “other income, net”.

Stock-Based Compensation Expense

The Company grants restricted stock and stock options to employees, consultants and directors. The Company recognizes stock-based compensation cost for awards with performance conditions if and when it concludes that it is probable that the performance conditions will be achieved. For awards with only a service condition, the Company expenses stock-based compensation on a straight-line basis over the requisite employee service period or for grants issued with performance conditions, on a graded-vesting basis over the requisite employee service period. The Company records stock-based compensation expense associated with grants of restricted stock and stock options in the consolidated statements of operations and comprehensive loss based on their estimated fair value at the date of the grant. The Company classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the grantee’s payroll costs are classified or in which the grantee’s service payments are classified. Forfeitures are accounted for as they occur.

Stock-based compensation expense related to non-performance employee stock options is measured using the fair value of the underlying award at the grant date. Stock-based compensation expense for these awards is then recognized on a straight-line basis over the vesting period, which is also the requisite service period.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. As there was no public market for the Company’s common stock prior to the initial public offering of its common stock in August 2020, the estimated fair value of common stock was determined by the Company’s board of directors as of the date of each option grant, with input from management, considering third-party valuations of its common stock, as well as the Company’s board of directors’ assessment of additional objective and subjective factors that it believed were relevant, and which may have changed from the date of the most recent third-party valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants’ Accounting and Valuation Guide, *Valuation of Privately Held Company Equity Securities Issued as Compensation*. Following the closing of the initial public offering, the fair value of the

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Company's common stock is determined based on the quoted market price of common stock. The Company also lacks company-specific historical and implied volatility information for its stock. The Company estimates its expected stock price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method. The "simplified" method estimates the expected term of stock options as the mid-point between the weighted average time to vesting and the contractual maturity. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. There is no expected dividend yield since the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Effective January 1, 2019, the Company adopted Accounting Standards Update ("ASU") No. 2018-07, Compensation—Stock Compensation (Topic 718): *Improvements to Non-employee Share-based Payment Accounting* ("ASU 2018-07"), which sets out to simplify the accounting for non-employee share-based payments. The ASU expands the scope of Topic 718, *Compensation—Stock Compensation*, which currently only includes share-based payments issued to employees, to also include share-based payments issued to non-employees for goods and services. Consequently, the accounting for share-based payments to non-employees and employees is substantially aligned. ASU 2018-07 impacts the value at which share-based payments to non-employees is recognized. Prior to the adoption of ASU 2018-07 for share-based payments granted to non-employees, including consultants, stock-based compensation expense was recognized over the period during which services were rendered by such non-employees until completed. At the end of each financial reporting period prior to completion of the service, the fair value of the unvested share-based payments was remeasured using the then-current fair value of the share-based payments. After adoption of ASU 2018-07, the measurement date for non-employee share-based payments are the date of the grant. The stock-based compensation expense for non-employees is recognized, without changes in the fair value of the share-based payments, over the requisite service period, which is the vesting period of the respective share-based payments. There was no material impact as a result of adopting this new standard.

Net Loss per Share

Basic and diluted net loss per share is determined by dividing net loss by the weighted-average common stock outstanding during the period. For all periods presented, outstanding stock options, unvested restricted common stock, Series A2 Preferred Stock, Series A3 Preferred Stock, Series A4 Preferred Stock and Series B Preferred Stock, have been excluded from the calculation because their effects would be anti-dilutive. Therefore, the weighted-average shares used to calculate both basic and diluted loss per share are the same.

Income Taxes

The Company accounts for income taxes under the asset and liability method in accordance with ASC 740, *Income Taxes*. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which these temporary differences are expected to be recovered or settled. Valuation allowances are provided if based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Management believes that it is more likely than not that all deferred tax assets will not be realized.

The Company recognizes liabilities for potential tax payments to various tax authorities related to uncertain tax positions. The liabilities are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filing is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Potential interest and penalties associated with such uncertain tax positions, if any, are recorded as components of income tax expense.

The Company assesses its income tax positions and records tax benefits for all years subject to examination based upon management's evaluation of the facts, circumstances and information available as of the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50 percent likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the consolidated financial statements.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that subject the Company to credit risk consist primarily of cash, cash equivalents, restricted cash and short-term investments. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and have not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Such deposits have and will continue to exceed federally insured limits. The Company has not experienced any losses on its cash deposits.

At December 31, 2020 and 2019, the Company had no off-balance sheet risk.

Foreign Currency Translation

The reporting currency of the consolidated financial statements is the U.S. dollar (“USD”). The functional currency for AlloVir International and AlloVir Italia is the euro.

Assets and liabilities are translated into USD at the exchange rate in effect on the balance sheet date. Equity balances, other than retained earnings, are translated at historical exchange rates. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated balance sheets. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the functional currency are included in “other income, net” in the consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss is defined as a change in equity of a business enterprise during a period, resulting from transactions from non-owner sources. Comprehensive loss includes net loss and certain changes in stockholder’s deficit that are excluded from net loss. The Company had a net change in available-for-sale securities and a foreign currency translation adjustment during the years ended December 31, 2020 and 2019, which met the criteria as other comprehensive income and, therefore, the Company’s comprehensive loss includes unrealized gains (losses) on those available-for-sale securities and foreign currency translation adjustments from foreign subsidiaries.

Preferred Stock

The Company applies the guidance enumerated in FASB ASC Topic 480, *Distinguishing Liabilities from Equity* (“ASC 480”), when determining the classification and measurement of preferred stock. Preferred stock subject to mandatory redemption (if any) are classified as liability instruments and are measured at fair value. The Company classifies conditionally redeemable preferred stock (if any), which includes preferred stock that features redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company’s control, as temporary equity. At all other times, the Company classifies its preferred stock in stockholders’ equity.

Leases

Effective January 1, 2019, the Company adopted and accounts for its leases under ASC 842, *Leases* (“ASC 842”), using the modified retrospective transition approach, as applied to the earliest comparative period presented. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease. Leases with a term greater than one year are recognized on the consolidated balance sheet as a right-of-use (“ROU”) asset and current and non-current lease liabilities, as applicable. The Company has made an accounting policy election, known as the short-term lease recognition exemption, which allows the Company to not recognize ROU assets and lease liabilities that arise from short-term leases (12 months or less) for any class of underlying asset. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew or options to cancel a lease are not included in the Company’s assessment unless there is reasonable certainty that the Company will renew or will not cancel, respectively. The Company monitors its material leases on a quarterly basis.

Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected remaining lease term. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Certain adjustments to the ROU asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its lease in determining the appropriate incremental borrowing rate.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company initially elected to account for lease and non-lease components together as a single component for all leases except manufacturing leases, the Company has since updated this policy and has elected to account for the lease and non-lease components together for all existing classes of underlying assets. The transactions under the previous policy election have been immaterial historically.

Subsequent Events

The Company evaluates events occurring after the date of our accompanying consolidated balance sheets for potential recognition or disclosure in our consolidated financial statements. The Company did not identify any material subsequent events requiring adjustment to our accompanying consolidated financial statements (recognized subsequent events). Those items requiring disclosure (unrecognized subsequent events) in the consolidated financial statements have been disclosed accordingly. Refer to Note 19 for further details.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board (“FASB”), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company’s consolidated financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended (the “JOBS Act”), the Company meets the definition of an emerging growth company and has elected the extended transition period for complying with certain new or revised accounting standards pursuant to Section 107(b) of the JOBS Act. As noted below, certain new or revised accounting standards were early adopted.

Recently Issued Accounting Pronouncements Not Yet Adopted

In December 2019, the FASB issued ASU 2019-12 – *Income Taxes (Topic 740)* (“ASU 2019-12”), which removes certain exceptions from the guidance and simplifies the accounting for income taxes in certain areas. The new standard will be effective beginning January 1, 2021. The Company does not expect that the new standard will have a material impact to the Company’s consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* (“ASU 2016-13”). ASU 2016-13 significantly changes the impairment model for most financial assets and certain other instruments. ASU 2016-13 will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets, which will generally result in earlier recognition of allowances for credit losses on loans and other financial instruments. ASU 2016-13 is effective for the Company’s fiscal year beginning December 15, 2022 and subsequent interim periods. The adoption of this standard is not expected to have a material impact on the Company’s consolidated financial statements and related disclosures.

3. Short-Term Investments

The following table summarizes the amortized cost and estimated fair value of the Company’s marketable securities, which are considered to be available-for-sale investments and were included in short-term investments on the consolidated balance sheets:

	December 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
(in thousands) U.S. government treasury securities	\$ 233,687	\$ —	\$ (24)	\$ 233,663
Totals	<u>\$ 233,687</u>	<u>\$ —</u>	<u>\$ (24)</u>	<u>\$ 233,663</u>

	December 31, 2019			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
(in thousands) U.S. government treasury securities	\$ 64,925	\$ 68	\$ —	\$ 64,993
Totals	<u>\$ 64,925</u>	<u>\$ 68</u>	<u>\$ —</u>	<u>\$ 64,993</u>

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Certain short-term debt securities with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheets and are not included in the tables above. At December 31, 2020 and 2019, 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:

(in thousands)	December 31, 2020				Total
	Level 1	Level 2	Level 3		
Cash equivalents:					
Money market fund	\$ 55,505	\$ —	\$ —	\$ —	\$ 55,505
U.S. government treasury securities	39,998	—	—	—	39,998
Totals	\$ 95,503	\$ —	\$ —	\$ —	\$ 95,503
Short-term investments:					
U.S. government treasury securities	\$ 233,663	\$ —	\$ —	\$ —	\$ 233,663
Totals	\$ 233,663	\$ —	\$ —	\$ —	\$ 233,663

(in thousands)	December 31, 2019				Total
	Level 1	Level 2	Level 3		
Cash equivalents:					
Money market fund	\$ 46,407	\$ —	\$ —	\$ —	\$ 46,407
Demand deposit	10,027	—	—	—	10,027
Totals	\$ 56,434	\$ —	\$ —	\$ —	\$ 56,434
Short-term investments:					
U.S. government treasury securities	\$ 64,993	\$ —	\$ —	\$ —	\$ 64,993
Totals	\$ 64,993	\$ —	\$ —	\$ —	\$ 64,993

During the years ended December 31, 2020 and 2019, 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 carrying amounts of unbilled grants receivable, prepaid expenses and other current assets, 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 lease liabilities and their corresponding ROU assets are recorded based on the present value of future lease payments over the expected remaining lease term. The Company has elected to account for the lease and non-lease components together for existing classes of underlying assets.

The Company leases an office space in Houston, Texas under an operating lease that expires in March 2021. The Company also sub-leases from ElevateBio a portion of its office space in Cambridge, Massachusetts on a month-to-month basis. Total expense recognized under short-term leases was \$0.4 million during the year ended December 31, 2020, including \$0.1 million non-lease costs such as utilities and cleaning, and \$0.3 million during the year ended December 31, 2019, including approximately \$43,000 for non-lease costs such as utilities and cleaning.

On March 26, 2019, the Company entered into an interim services agreement which ultimately led to a Development and Manufacturing Services Agreement (“DMS Agreement”) with a third-party supplier on July 19, 2019. The DMS Agreement specifies a dedicated manufacturing suite with 2 production lines for the manufacture of AlloVir’s products at the facility.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The DMS Agreement will expire upon the later of: 1) two years from the Effective Date, or July 19, 2021, and 2) the completion of services under all Statements of Work (SOWs). The term may be extended by agreement of the parties for additional two-year periods upon written notice to the supplier at least 30 days prior to expiration of the then-current term. The DMS Agreement (or any individual SOW) may be terminated earlier by AlloVir at any time by providing 190 days' notice. The Company estimates that the exercise of one of the two-year renewal options is reasonably certain to occur, and that early termination is not reasonably certain to occur, providing for a total estimated lease term of 4.25 years expiring in July 2023. In March 2019, at the inception of this lease, the Company recorded a ROU asset and lease liability for \$6.9 million. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. ROU assets and liabilities are recognized at lease commencement date based on the present value of the lease payments over the lease term. The Company uses its incremental borrowing rate based on information available at commencement date in determining the present value of lease payments. The incremental borrowing rate represents the rate of interest that a lessee would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. The Company estimated these rates based on prevailing market conditions, comparable company and credit analysis, the impact of collateralization, the term of each of the Company's lease agreements and management judgment. In September 2019, the Company executed a SOW for another dedicated manufacturing suite under the DMS Agreement with substantially the same terms as the original SOW. The SOW calls for a fixed monthly payment through July 2023, with additional two-year renewal options. The use of this manufacturing suite qualifies as a lease under ASC 842, as it includes an identified asset for exclusive use by the Company at its direction.

Maturities of operating lease liabilities at December 31, 2020 are as follows (in thousands):

2021	\$ 3,600
2022	3,600
2023	2,100
2024	—
Total lease payments	9,300
Less: interest (4.53% - 5.75%)	(608)
Total lease liability	\$ 8,692
Lease liability – current	\$ 3,229
Lease liability – long-term	\$ 5,463

Total lease costs were \$4.0 million and \$2.1 million for the years ended December 31, 2020 and 2019, respectively. Cash paid for operating leases was \$3.6 million for the year ended December 31, 2020. The Company's total variable non-lease costs, such as materials, non-fixed batch payments, storage, tech transfer and other common area maintenance fees, related to the operating leases was \$4.5 million and \$1.8 million for the years ended December 31, 2020 and 2019, respectively. The weighted average remaining lease term is 2.58 years at December 31, 2020. The weighted average discount rate is 5.14%.

In May 2020, the Company entered into a new Development and Manufacturing Services Agreement ("2020 DMS Agreement") with ElevateBio BaseCamp, Inc. and signed a statement of work (SOW) in November 2020. The DMS Agreement and related SOW contained an embedded lease for a dedicated manufacturing suite for the manufacture of AlloVir's products at the facility, which had not yet commenced at December 31, 2020. In exchange for this dedicated manufacturing suite, AlloVir will pay the supplier a monthly fixed suite reservation fee, totaling \$3.0 million over the two year lease term (one year lease with a one year renewal option), that covers costs associated with reserving capacity for AlloVir as well as cleaning services, utilities, handling and maintenance of the manufacturing suite. At December 31, 2020, \$0.6 million of the \$3.0 million was prepaid under this arrangement.

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

(in thousands)	December 31,	
	2020	2019
Equipment	\$ 368	\$ 339
Construction-in-progress	536	30
Total property and equipment	904	369
Less: accumulated depreciation	(92)	(19)
Property and equipment, net	\$ 812	\$ 350

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Depreciation expense was \$0.1 million and approximately \$19,000 for the years ended December 31, 2020 and 2019, respectively.

7. Accrued Expenses

Accrued expenses consisted of the following:

(in thousands)	December 31,	
	2020	2019
Employee compensation and benefits	\$ 3,314	\$ 1,520
Professional fees	696	445
Research and development	3,347	3,051
Other	173	147
Total accrued expenses	\$ 7,530	\$ 5,163

8. Sponsored Research, Collaboration and License Agreements

Amended and Restated Exclusive License Agreement with BCM

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

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

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

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

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

Exclusive License Agreement with BCM

In November 2020, the Company signed a second License Agreement (the “Second License Agreement) with BCM, whereby the Company acquired a royalty-bearing, worldwide, exclusive license to BCM’s rights in Subject Technology and related patent rights outside the field of viral infection (all fields other than those covered by the A&R License Agreement).

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

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

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

Sponsored Research Agreement with BCM

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

Collaboration Agreement with BCM

In November 2020, the Company also entered into a Research Collaboration Agreement (the “Research Agreement”) with BCM, under which the Company agreement to pay BCM for performing certain research activities under the direction of Dr. Ann Leen commencing on January 1, 2021 and continuing for a three-year period thereafter. The Research Agreement requires the Company to make payments to BCM totaling approximately \$2.0 million per year, for a total of approximately \$6.0 million over the term of the Research Agreement.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Collectively under the agreements above and for services provided by BCM the Company paid \$1.1 million and \$0.9 million during the years ended December 31, 2020 and 2019, respectively, and the payments were classified in research and development expense in the consolidated statements of operations and comprehensive loss.

Primarily all costs incurred related to services provided by BCM under the license agreements and SRA-2 discussed above qualify for reimbursement under the Company's grant discussed in Note 10. Consideration received under the CPRIT Grant is recognized within grant revenue under ASC 606 in the consolidated statements of operations and comprehensive loss. Reimbursements for qualifying expenses incurred under all other grants are recognized within "other income, net" in the consolidated statements of operations and comprehensive loss.

9. Revenue

CPRIT GRANT

In August 2017, the Company was awarded a \$9.0 million grant (the "CPRIT Grant") from the Cancer Research and Prevention Institute of Texas ("CPRIT") to perform a phase IIB clinical trial to establish the safety and effectiveness of Viralym-M, in adults and children with a common, very severe virus infection (BK Virus) after stem cell transplant. The grant period was three years beginning September 1, 2017 through August 31, 2020. This grant had a matching requirement where the Company was obligated to match 50% of the grant funds used on the project. In addition, the grant included other compliance requirements including the obligation for the Company to operate with a principal place of business in Texas. There were no costs incurred to obtain or fulfill the contract. In November 2019, the Company provided CPRIT with written notice of its intent to terminate the grant. In December 2019, the Company returned \$2.6 million of grant funds received, including interest relating to these funds in the amount of \$0.1 million, and decreased its deferred revenue balance to zero. The Company received acknowledgment of the termination from CPRIT in January 2020.

In addition to the requirements above, the CPRIT Grant also required that the Company grant CPRIT a non-commercial license to technology developed under the grant and pay CPRIT a share of revenue on sales of commercial products developed using CPRIT funds equal to low single digits of revenue until such time as CPRIT has been paid an aggregate amount equal to 400% of the grant award proceeds. No royalty payments were made under this license agreement during the years ended December 31, 2020 and 2019, respectively.

The Company accounted for the CPRIT Grant under ASC 606, as CPRIT represents a customer to the Company and the performance obligations are clearly defined within the arrangement. Revenue recognized during the year ended December 31, 2019 from amounts included in the contract liability at the beginning of the period was \$0.2 million.

The following table presents the changes in the Company's contract liabilities during the year ended December 31, 2019:

(in thousands)	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract liabilities:				
Deferred revenue	\$ 2,663	\$ —	\$ (2,663)	\$ —

10. Funding Arrangements

SBIR Grant

In June 2017, the Company was awarded a Small Business Innovation Research ("SBIR") grant by NIH in the amount of \$3.0 million. This grant was effective from September 15, 2017 to March 30, 2020 and in April 2020, the Company received an extension through March 31, 2021. The grant is funded on an ongoing basis based on periodic reports of qualifying expenditures by the Company to NIH. Under this grant, the Company received \$0.9 million and \$1.0 million during the years ended December 31, 2020 and 2019, respectively. The Company recognized income of \$0.6 million and \$0.9 million on incurred expenses during the years ended December 31, 2020 and 2019, respectively. At December 31, 2020, the Company had received the full amount awarded under the SBIR grant.

The SBIR grant does not fall within the scope of ASC 606 as NIH does not meet the definition of a customer, and the grants from NIH were given for the benefit of public health rather than for monetary compensation. Accordingly, funding received under this grant is recognized in "other income, net" in the consolidated statements of operations and comprehensive loss.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

11. Convertible Preferred Stock

On August 3, 2020, upon the closing of the Company's IPO, all of the then-outstanding shares of convertible preferred stock automatically converted into 39,859,139 shares of common stock. There were no outstanding shares of preferred stock at December 31, 2020.

At December 31, 2019, preferred stock consisted of the following:

(in thousands, except share amounts)	December 31, 2019				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A1 Preferred Stock	20,000,000	—	\$ —	\$ —	—
Series A2 Preferred Stock	20,000,000	20,000,000	29,775	30,000	13,420,970
Series A3 Preferred Stock	22,453,987	22,453,987	19,364	33,681	15,067,706
Series A4 Preferred Stock	2,066,666	2,066,666	3,065	3,100	1,386,831
Series B Preferred Stock	<u>14,877,697</u>	<u>14,877,697</u>	<u>120,923</u>	<u>121,253</u>	<u>9,983,632</u>
Total	<u>79,398,350</u>	<u>59,398,350</u>	<u>\$ 173,127</u>	<u>\$ 188,034</u>	<u>39,859,139</u>

The holders of Series A1, A2, A3, and A4 Preferred Stock (collectively referred to as "holders of Series A Preferred Stock" unless noted) and Series B Preferred Stock, had the following rights and preferences:

Voting

The holders of preferred stock were entitled to the same voting rights as the holders of common stock, with a number of votes equal to the number of common stock into which such preferred stock would be converted. The holders of a majority of the then outstanding preferred stock had the right to vote upon any matter submitted to the shareholders for a vote. Except for holders of Series A4 Preferred Stock, which is non-voting.

Certain matters, prior to being able to be undertaken by the Company, required the affirmative vote of the holders of preferred stock, voting separately as a single class. These matters included amending the Certificate of Incorporation, authorizing new shares of stock, liquidating the business, selling or licensing material assets, changing Board of Director composition and other matters. In addition, certain matters required the affirmative vote of the holders of Series B Preferred Stock, including the amendment of the Certificate of Incorporation or Bylaws in a manner that adversely affects the powers, preferences, rights or privileges of the Series B Preferred Stock, certain purchases or redemptions of capital stock and any changes in the number of authorized shares of Series B Preferred Stock.

Conversion

At the option of the holder, all preferred stock was convertible into common stock at any time after the date of issuance. The initial conversion price was equal to the original issue price per share (\$1.50 for Series A Preferred Stock and \$8.15 for Series B Preferred Stock) and was subject to adjustment as disclosed in Certificate of Incorporation. Each share of preferred stock automatically converted into common stock at the applicable conversion rate upon either (a) the affirmative election of the required holders or (b) the closing of an underwritten public offering on the New York Stock Exchange or NASDAQ with gross proceeds of at least \$100.0 million.

Dividends

The holders of preferred stock were entitled to non-cumulative dividends of 8% of the original issue price, payable when, and if, declared by the Board of Directors. Dividends for Series A Preferred Stock are only paid after payment in full of dividends for Series B Preferred Stock.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Liquidation Preference

In the event of a liquidation of the Company, the holders of Series B Preferred Stock were entitled to be paid, in preference to Series A Preferred Stock and common stock, the greater of 1) the Series B Preferred Stock original issue price of \$8.15 per share, plus any dividends declared but unpaid or 2) the amount per share that would have been payable had all shares of Series B Preferred Stock been converted into common stock at the time of the liquidation (the “Series B Liquidation Preference”). If amounts upon liquidation were insufficient to pay the Series B Preferred Stock, the holders of Series B Preferred Stock would share ratably in the distribution of the assets based on the distribution that would have otherwise been paid in full.

In the event of a liquidation of the Company, after payment of the Series B Liquidation Preference, the holders of Series A Preferred Stock were entitled to be paid, in preference to common stock, the greater of 1) the Series A Preferred Stock original issue price of \$1.50 per share, plus any dividends declared but unpaid or 2) the amount per share that would have been payable had all shares of Series A Preferred Stock been converted into common stock at the time of the liquidation (the “Series A Liquidation Preference”). If amounts upon liquidation were insufficient to pay the Series A Preferred Stock, the holders of Series A Preferred Stock would share ratably in the distribution of the assets based on the distribution that would have otherwise been paid in full.

Redemption

The Company determined that all series of preferred stock were redeemable, based on the Certificate of Incorporation that states upon the occurrence of a deemed liquidation event, the holders of preferred stock were entitled to receive cash or other assets. Additionally, the deemed liquidation events are not in the sole control of the Company and the preferred stock does not meet any limited exceptions under ASC 480, *Distinguishing Liabilities From Equity*. As such, the Company classified its preferred stock outside of permanent equity and into mezzanine equity.

Covenant to Purchase Crossover Securities

Upon the occurrence of a decrease in the Company’s cash or on the occurrence of a crossover round, the Company would have been required to issue additional preferred stock and ElevateBio would have been required to purchase such shares with an aggregate purchase price of \$20.0 million, with the number of shares imputed based on the estimated fair value per share at that time. The Company evaluated whether this feature represented an embedded derivative or a freestanding financial instrument and concluded that the obligation to issue additional shares represented a contingent forward that should be accounted for at fair value. The Company concluded that the fair value at issuance and at December 31, 2018 was *de minimis* based on the probabilities of such events occurring at such dates. The contingent forward was settled on May 8, 2019 in conjunction with the issuance of Series B Preferred Stock.

Make Whole Provisions

The preferred stock agreements contained various make whole provisions upon the occurrence of certain events, such as stock splits, recapitalizations, etc. The Company evaluated whether these features represent embedded derivatives or free-standing financial instruments and concluded that the features represent a derivative embedded within the agreement which requires bifurcation and to be recorded at fair value. At issuance and August 3, 2020, upon conversion to common stock at completion of our IPO, the Company concluded that the fair value was *de minimis* based on the probabilities of such events occurring at such dates.

12. Stockholder’s Equity (Deficit)

On August 3, 2020, in connection with the closing of the Company’s IPO, the Company filed its amended and restated certificate of incorporation, which authorizes the Company to issue up to 10,000,000 shares of preferred stock, \$0.0001 par value per share. There are no shares of preferred stock issued or outstanding at December 31, 2020.

At December 31, 2020, the Company’s amended and restated certificate of incorporation authorized the Company to issue 150,000,000 shares of common stock at a par value of \$0.0001 per share. In conjunction with the Company’s IPO closing on August 3, 2020, the Company issued and sold 18,687,500 shares of its common stock, including 2,437,500 shares pursuant to the full exercise of the underwriters’ option to purchase additional shares, at a public offering price of \$17.00 per share, for aggregate net proceeds of \$292.0 million after deducting underwriting discounts and commissions and offering costs. In connection with the Company’s IPO, all outstanding shares of preferred stock converted into 39,859,139 shares of common stock.

The following is a summary of the rights and privileges of the holders of the Company’s common stock at December 31, 2020 and 2019:

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Voting Rights

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders (and written actions in lieu of meetings), and there are not any cumulative voting rights. The number of authorized shares of common stock may be increased or decreased by the affirmative vote of the holders of shares of capital stock of the Company; however, the issuance of common stock may be subject to the vote of the holders of one or more series of preferred stock that may be required by terms of the Third Amended and Restated Certificate of Incorporation.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the Board out of legally available funds. At December 31, 2020, no cash dividends have been declared or paid.

Liquidation Preference

In the event of a liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all debts and other liabilities and the satisfaction of any liquidation preference granted to the then-outstanding shares of preferred stock.

Rights and Preferences

Holders of common stock have no preemptive, conversion or subscription rights and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that the Company may designate in the future.

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

	December 31,	
	2020	2019
Preferred stock	—	39,859,139
Unvested restricted stock	3,410,979	4,403,148
Options to purchase common stock	3,972,909	44,960
Stock available for grant under the 2018 Equity Incentive Plan	—	486,082
Stock available for grant under the 2020 Stock Option and Grant Plan	3,895,961	—
Total	<u>11,279,849</u>	<u>44,793,329</u>

13. Stock-Based Compensation

2018 Equity Incentive Plan

The Company's 2018 Plan provided for the Company to issue restricted stock, restricted stock units, incentive stock options, and non-statutory stock options and other stock-based awards to employees, officers, members of the Board, consultants and advisors of the Company. The 2018 Plan was most recently amended in July 2020. The awards granted under this plan generally vest over a four-year period and have a 10-year contractual term.

At December 31, 2020, the Company had granted 6,715,415 shares of common stock under the 2018 Plan, including an aggregate of 98,643 shares of common stock issuable upon the exercise of outstanding options under the 2018 Plan. Of the awards granted, 6,710 have been forfeited or cancelled. No shares remained available for future issuance under the 2018 Plan. Any options or awards outstanding under the 2018 Plan remain outstanding and effective.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

2020 Stock Option and Grant Plan

On July 2, 2020, the Company's Board of Directors adopted and in July 2020 the stockholders approved the 2020 Stock Option and Grant Plan (the "2020 Plan") which became effective on July 28, 2020, the date immediately prior to the date on which the registration statement related to the IPO was declared effective, and as a result no further awards will be made under the 2018 Plan thereafter. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2020 Plan will be 8,008,734 shares. The number of shares of our common stock reserved for issuance under the 2020 Plan shall be cumulatively increased on January 1, 2021 and each January 1 thereafter by 5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall. Accordingly, on January 1, 2021, 3,255,343 shares were added to the number of available shares under the 2020 Plan. The awards granted under this plan generally vest over a four-year period and have a 10-year contractual term.

At December 31, 2020, there were an aggregate of 3,874,266 shares of common stock issuable upon the exercise of outstanding options under the 2020 Plan and 238,507 shares of restricted common stock granted under the 2020 Plan. Additionally, there were an aggregate of 3,895,961 shares reserved for future issuance under the 2020 Plan.

Restricted Common Stock

The Company granted 315,023 shares of restricted stock to employees in 2020. Stock-based compensation expense for restricted stock was \$3.6 million for the year ended December 31, 2020.

The Company granted 2,434,515 shares of restricted common stock to employees in 2019. Stock-based compensation expense for restricted stock was \$2.9 million for the year ended December 31, 2019.

Under the 2018 Plan the Company granted restricted common stock awards with service conditions. In May 2020, two employees grants were modified to include both a service and performance condition. Stock compensation is recognized over the vesting period based on the probability of achievement of the performance condition. The performance condition was based on the Company's completion of its IPO, which was consummated on August 3, 2020. The awards earned upon satisfaction of the performance condition will become fully vested on the fourth anniversary of the vesting commencement date of the award (i.e. continued service is required beyond the satisfaction of the performance condition prior to vesting). At December 31, 2020, the performance condition was met and compensation expense of \$1.7 million related to these performance-based awards has been recorded.

The following table summarizes restricted common stock activity for the year ended December 31, 2020:

	Shares	Weighted Average Grant Date Fair Value
Unvested at January 1, 2020	4,403,148	\$ 1.87
Granted	315,023	21.07
Forfeited	(22,316)	19.25
Vested	<u>(1,284,876)</u>	<u>1.84</u>
Unvested at December 31, 2020	<u>3,410,979</u>	<u>\$ 3.55</u>

The weighted average grant date fair value of restricted stock granted in 2019 was \$2.93 per share and the weighted average grant date fair value of restricted stock vested in 2019 was \$1.80. At December 31, 2020, there was \$10.4 million of unrecognized stock-based compensation cost related to the restricted stock, which is expected to be recognized over a weighted average period of 3.02 years.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Stock Options

The following table summarizes stock option activity (in thousands, except share and per share data):

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Life	Aggregate Intrinsic Value
Options outstanding at January 1, 2020	44,960	\$ 3.01	9.5	\$ —
Granted	3,952,949	18.08	—	—
Forfeited	(25,000)	27.97	—	226
Exercised	—	—	—	—
Options outstanding at December 31, 2020	3,972,909	\$ 17.84	9.6	\$ 81,822
Options vested and exercisable at December 31, 2020	20,609	\$ 5.56	8.9	\$ 678

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 in 2020 and 2019 was \$13.77 per share and \$2.17 per share, respectively. At December 31, 2020, there was \$48.1 million of unrecognized stock-based compensation expense related to unvested stock options, which is being recognized over a period of 3.53 years.

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

	Year Ended December 31,	
	2020	2019
Expected term (in years)	6.08	6.25
Expected volatility	95%	84%
Risk-free interest rate	0.36%	1.65%
Expected dividend yield	—	—
Fair value of common stock	\$ 18.08	\$ 3.01

Stock-Based Compensation Expense

Stock-based compensation expense was as follows:

(in thousands)	Years Ended December 31,	
	2020	2019
Research and development	\$ 3,571	\$ 547
General and administrative	5,858	2,343
Total stock-based compensation expense	\$ 9,429	\$ 2,890

2020 Employee Stock Purchase Plan

In July 2020, the 2020 Employee Stock Purchase Plan (the "2020 ESPP") was also adopted by the Board of Directors and approved by the stockholders. The purpose of the 2020 ESPP is to provide eligible employees of the Company and other designated companies, with opportunities to purchase shares of the Company's common stock, par value \$0.0001 per share. 611,354 shares of common stock in the aggregate have been approved and reserved for this purpose, plus on January 1, 2021 and each January 1 thereafter until January 1, 2030, the number of shares of common stock reserved and available for issuance under the Plan shall be cumulatively increased by the least of (i) 1,222,707 shares of common stock, (ii) 1% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, and (iii) such number of shares of common stock as determined by the Administrator. The Board of Directors elected not to increase the number of available shares as of January 1, 2021.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

14. Income Taxes

The Company accounts for income taxes under the asset and liability method in accordance with ASC 740, Income Taxes. Under this method, deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted rates in effect for the year in which these temporary differences are expected to be recovered or settled. Valuation allowances are provided if based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. Management believes that it is more likely than not that all deferred tax assets will not be realized.

The Company recognizes liabilities for potential tax payments to various tax authorities related to uncertain tax positions. The liabilities are based on a determination of whether and how much of a tax benefit taken by the Company in its tax filing is more likely than not to be realized following resolution of any potential contingencies present related to the tax benefit. Potential interest and penalties associated with such uncertain tax positions, if any, are recorded as components of income tax expense.

The Company assesses its income tax positions and records tax benefits for all years subject to examination based upon management's evaluation of the facts, circumstances and information available as of the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50 percent likelihood of being realized upon ultimate settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the consolidated financial statements.

Income (loss) before provision for income taxes consisted of the following:

(in thousands)	Year Ended December 31,	
	2020	2019
Federal	(68,356)	(23,839)
Foreign	(1,428)	—
Loss before provision for income taxes	\$ (69,784)	\$ (23,839)

The Company's income tax expense (benefit) for the years ended December 31, 2020 and 2019 relating to federal and state tax jurisdictions differs from the amounts determined by applying the statutory federal income tax rate based on the following:

(in thousands)	Years Ended December 31,	
	2020	2019
Benefit at the federal rate	\$ (14,655)	21.0%
Increase (decrease) resulting from:		
State taxes, net of federal benefit	(1,943)	2.8%
Change in valuation allowance	17,756	(25.4%)
R&D tax credits	(1,220)	1.7%
Other	62	(0.1%)
Total Income Tax Expense/(Benefit)	\$ —	\$ —

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Components of deferred income taxes consist of the following:

(in thousands)	December 31,	
	2020	2019
Deferred tax assets:		
Net operating loss carryforwards	\$ 20,866	\$ 7,604
Operating lease liabilities	2,244	2,747
Non-qualified stock compensation	1,326	—
R&D tax credits	2,215	753
Other	910	183
Total deferred tax assets	27,561	11,287
Valuation allowance	(24,555)	(6,799)
Net deferred tax asset (liability)	\$ 3,006	\$ 4,488
Deferred tax liabilities:		
Operating lease right-of-use assets	(2,244)	(2,747)
Restricted stock compensation	(629)	(1,650)
Depreciation	(65)	(75)
Other	(68)	(16)
Total deferred tax liabilities	(3,006)	(4,488)
Net deferred tax asset (liability)	\$ —	\$ —

The Company's accounting for deferred taxes involves the evaluation of a number of factors concerning the realizability of its net deferred tax assets. The Company primarily considered such factors as its history of operating losses, the nature of the Company's deferred tax assets, and the timing, likelihood and amount, if any, of future taxable income during the periods in which those temporary differences and carryforwards become deductible. At December 31, 2020 and 2019, the Company does not believe that it is more likely than not that the deferred tax assets will be realized; accordingly, a full valuation allowance has been established and no deferred tax asset is shown in the accompanying consolidated balance sheets. For the year ended December 31, 2020, the valuation allowance for deferred tax assets increased by \$17.8 million, which was principally due to the net operating loss.

At December 31, 2020 and 2019, the Company had unused federal net operating loss carryforwards of \$88.6 million and \$32.8 million, respectively. The federal net operating loss carryforwards have no expiration. The CARES Act temporarily allows the Company to carryback net operating losses arising in 2018, 2019 and 2020 to the five prior tax years. In addition, net operating losses generated in these years could fully offset prior year taxable income without the 80% of the taxable income limitation under the TCJA which was enacted on December 22, 2017. The Company has been generating losses since its inception, as such the net operating loss carryback provision under the CARES Act is not applicable to the Company.

At December 31, 2020 and 2019, the Company had unused state net operating loss carryforwards of \$31.7 million and \$11.4 million, respectively. The state net operating loss carryforwards expire in 2039.

At December 31, 2020 and 2019, the Company had \$1.8 million and \$0.6 million of research and development tax credit carryforwards that may be available to offset future federal income taxes through 2040. At December 31, 2020 and 2019, the Company also had \$0.5 million and \$0.2 million of research and development tax credit carryforwards that may be available to offset future state income taxes in the state of Massachusetts through 2035.

Utilization of net operating loss and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986, as amended, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of net operating loss and research and development tax credit carryforwards that can be utilized annually to offset future taxable income and tax expense, respectively. The Company has completed several financings since its inception which may result in a change of control as defined in Section 382 of the Internal Revenue Code or could result in a change in control in the future.

The Company complies with the provisions of ASC 740 in accounting for its uncertain tax positions. ASC 740 addresses the determination of whether tax benefits claimed or expected to be claimed on a tax return should be recorded in the consolidated financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. At December 31, 2020 and 2019, the Company had no uncertain tax positions.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

The Company recognizes interest accrued related to unrecognized tax benefits and penalties in income tax expense. The Company had no accruals for interest and penalties at December 31, 2020 and 2019.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. The statute of limitations for assessment by the Internal Revenue Service and state tax authorities remains open for the tax years December 31, 2018 through December 31, 2020 as the Company was incorporated in September 2018. There are currently no federal or state income tax audits in progress. The resolution of tax matters is not expected to have a material effect on the Company's consolidated financial statements.

15. 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)	Years Ended December 31,	
	2020	2019
Numerator:		
Net loss – basic and diluted	\$ (69,784)	\$ (23,839)
Denominator:		
Weighted-average common shares outstanding – basic and diluted	26,897,390	1,285,933
Net loss per share – basic and diluted	\$ (2.59)	\$ (18.54)

Based on the amounts outstanding at December 31, 2020 and 2019, the Company excluded the following potential shares of common stock from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2020 and 2019, because including them would have had an anti-dilutive effect. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

	Years Ended December 31,	
	2020	2019
Series A2 Preferred Stock	—	13,420,970
Series A3 Preferred Stock	—	15,067,706
Series A4 Preferred Stock	—	1,386,831
Series B Preferred Stock	—	9,983,632
Options to purchase common stock	3,972,909	44,960
Unvested restricted stock	3,410,979	4,403,148

16. Commitments and Contingencies

Leases

The Company leases an office space in Houston, Texas under an operating lease that expires in March 2021. The Company also subleases from ElevateBio a portion of its office space in Cambridge, Massachusetts on a month-to-month basis. See Note 5 for additional information.

Purchase Obligation

The Company has entered into a DMS Agreement (see Note 5) whereby the Company is required to purchase at least one batch of product per month for both dedicated manufacturing suites, totaling \$0.3 million per month, regardless of the Company's demand. The monthly batch product purchases related to the DMS Agreement will cease in July 2023.

Legal Proceedings

From time to time, in the ordinary course of business, the Company is subject to litigation and regulatory examinations as well as information gathering requests, inquiries and investigations. At December 31, 2020, there were no matters which would have a material impact on the Company's financial results.

ALLOVIR, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

17. Related Party Transactions

The Company entered into an agreement with ElevateBio that provides for ongoing services to the Company in areas such as accounting operations, public relations, information technology, human resources and administration management, finance and risk management, marketing services, facilities, procurement and travel and corporate development and strategy (the “Shared Services Agreement”). The Company was billed quarterly 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 Company also subleases office space, which includes payment for common area charges. The Company also has a SOW to receive manufacturing and project management consulting services from ElevateBio. During the year ended December 31, 2020, the Company recorded expenses of \$7.3 million, including a prepaid of \$0.9 million related to services provided to the Company by ElevateBio and affiliates. During the year ended December 31, 2019, the Company recorded expenses of \$3.2 million related to services provided to the Company by ElevateBio and affiliates. The Company owed ElevateBio \$0.6 million and \$0.2 million at December 31, 2020 and 2019, respectively, which is recorded in “Amount due to related party” on the consolidated balance sheets.

Members of the Company’s management received a total of \$0.6 million and \$0.4 million in consulting fees during the years ended December 31, 2020 and 2019 respectively.

18. Employee Benefit Plans

Effective January 1, 2019, the Company adopted a 401(k) Plan for its employees, which is designed to be qualified under Section 401(k) of the Internal Revenue Code. Eligible employees are permitted to contribute to the 401(k) Plan within statutory and 401(k) Plan limits. The Company made matching contributions of \$0.1 million for the years ended December 31, 2020 and 2019.

19. Subsequent Events

For the financial statements at December 31, 2020 and for the year then ended , the Company has evaluated all subsequent events through February 12, 2021, the date the consolidated financial statements were available to be issued, noting there were no events or matters identified that require additional disclosure.