

PROSPECTUS



COMMON STOCK

We are offering 16,250,000 shares of our common stock. This is our initial public offering and prior to this offering, no public market has existed for our shares. The initial public offering price is \$17.00 per share. Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol "ALVR."

We are an "emerging growth company" as defined under the U.S. federal securities laws and, as such, may elect to comply with reduced public company reporting requirements for this and future filings. See "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves a high degree of risk. See "[Risk Factors](#)" beginning on page 15.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	<u>Price to Public</u>	<u>Underwriting Discounts and Commissions</u>	<u>Proceeds to Company(1)</u>
Per share	\$17.00	\$1.19	\$15.81
Total	\$276,250,000	\$19,337,500	\$256,912,500

(1) See "Underwriting" for a description of the compensation payable to the underwriters.

We have granted the underwriters an option for a period of 30 days to purchase up to 2,437,500 additional shares of common stock.

The underwriters expect to deliver the shares of common stock to purchasers on August 3, 2020.

MORGAN STANLEY

J.P. MORGAN

SVB LEERINK

PIPER SANDLER

Prospectus dated July 29, 2020

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We are responsible for the information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with any other information other than that in this prospectus. We take no responsibility for and can provide no assurance as to the reliability of, and the underwriters have not taken responsibility for and can provide no assurance as to the reliability of, any other information others may give you. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

Through and including August 23, 2020 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Numerical figures included in this prospectus have been subject to rounding adjustments. Accordingly, numerical figures shown as totals in various tables may not be arithmetic aggregations of the figures that precede them.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes included elsewhere in this prospectus and the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” As used in this prospectus, unless the context otherwise requires, references to “AlloVir,” the “Company,” “we,” “us” and “our” refer to AlloVir, Inc. and, where appropriate, our subsidiaries.

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 of which has successfully completed a proof-of-concept trial across five viruses and is entering initial pivotal trials for the treatment of virus-associated hemorrhagic cystitis in the fourth quarter of 2020.

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 initiate a total of three Phase 3 pivotal and three Phase 2 proof-of-concept trials in 2020 and 2021 for the treatment and prevention of life-threatening viral diseases in pediatric and/or adult patients, each representing a potential meaningful commercial opportunity.

Based on the data generated from our Phase 2 proof-of-concept trial and the critical medical need, Viralym-M has been granted PRIME, 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 also 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. To date, Viralym-M is one of only 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.

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

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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 therapy candidates that can be delivered to individuals with compromised immune systems and those who are at high risk, or suffering from, the life-threatening consequences of viral diseases. We expect to have three cell therapies in the clinic by the end of 2020.

Our Pipeline

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. To address this need, 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.

THERAPY CANDIDATE	TARGET INDICATION	TARGET POPULATION	PRECLINICAL	POC TRIAL (Phase 1b/2)	PIVOTAL TRIAL (Phase 3)
Viralym-M (ALVR105) Multi-VSTs targeting BKV, CMV, AdV, EBV, and HHV-6	Treatment of Virus-Associated Hemorrhagic Cystitis	Allo-HSCT	▶		
	Treatment of CMV	Allo-HSCT	▶		
	Treatment of AdV	Allo-HSCT	▶		
	Prevention of BKV, CMV, AdV, EBV, HHV-6 and JCV	Allo-HSCT	▶		
	Treatment of BKV	KT	▶		
	Treatment of CMV	SOT	▶		
ALVR106 Multi-VSTs targeting RSV, Influenza, PIV and hMPV	Treatment of RSV, Influenza, PIV, and hMPV	Allo-/Auto-HSCT	▶		
	Treatment of RSV, Influenza, PIV, and hMPV	High-risk general population	▶		
ALVR109 Single-VSTs targeting SARS-CoV-2	Treatment of COVID-19	High-risk general population	▶		
ALVR107 Single-VSTs targeting HBV	Treatment of HBV	Patients with chronic HBV	▶		
ALVR108 Single-VSTs targeting HHV-8	Treatment of HHV-8	Patients with KS, MCD or PEL	▶		

POC: Proof-of-concept; Allo-HSCT: Allogeneic HSCT; Auto-HSCT: Autologous HSCT; KT: Kidney Transplant; SOT: Solid Organ Transplant; KS: Kaposi Sarcoma; MCD: Multicentric Castlemans Disease; PEL: Primary Effusion Lymphoma

Viralym-M (ALVR105) is an allogeneic, off-the-shelf VST therapy 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. We plan to initiate three Phase 3 pivotal trials and three Phase 2 proof-of-concept trials of Viralym-M in 2020 and 2021.

Given that our VST product candidate targets multiple viruses, Viralym-M has multiple potential applications. We are initially focusing the development of Viralym-M in allogeneic HSCT and SOT patients who are at high risk for life-threatening viral infections as follows:

- Treatment of Virus-Associated HC (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)

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- Treatment of BKV Infections in Kidney Transplant Patients
- Treatment of CMV Infections in SOT Patients

ALVR106 is an allogeneic, off-the-shelf VST therapy developed to target devastating diseases caused by four respiratory viruses: respiratory syncytial virus, or RSV, influenza, parainfluenza virus, or PIV, and human metapneumovirus, or hMPV. We anticipate submitting an Investigational New Drug, or IND, application with the FDA for ALVR106 in the second half of 2020 covering infections and diseases caused by influenza, PIV, RSV and hMPV, and plan to initiate our Phase 1/2 clinical study in HSCT patients and other high risk individuals such as immunocompromised cancer patients, the elderly and very young with immature immune systems diseases in the fourth quarter of 2020.

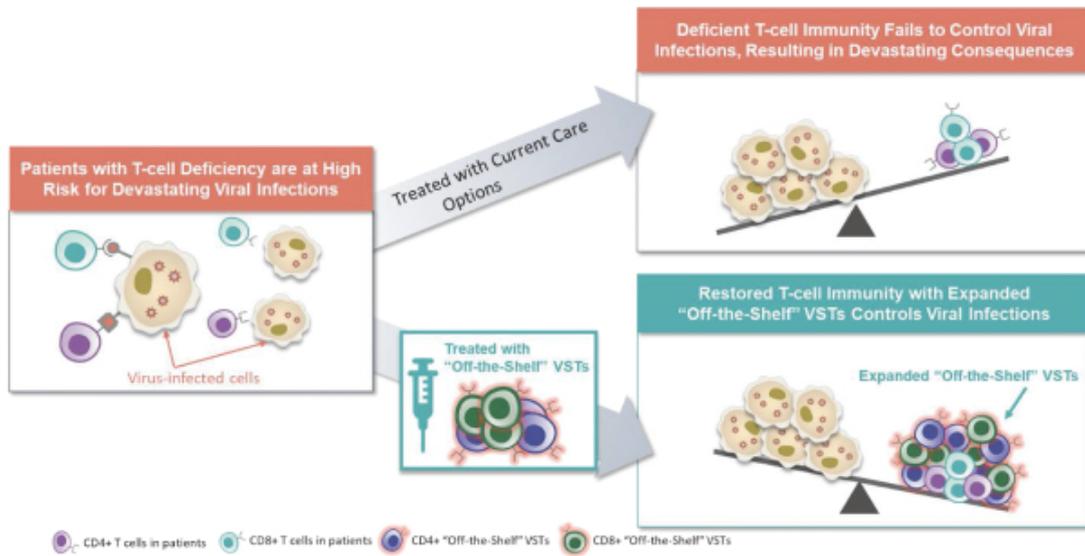
ALVR109 is an allogeneic, off-the-shelf VST therapy designed to target SARS-CoV-2, the virus that causes the severe and life-threatening viral disease, COVID-19. ALVR109 is being developed to arrest the progression of COVID-19 by eradicating SARS-CoV-2 virus-infected cells. In its capacity as trial sponsor, Baylor College of Medicine, or BCM, submitted an IND application with the FDA for ALVR109 in June 2020. In July 2020, the IND was placed on clinical hold for safety concerns related to the quality of ancillary reagents unique to ALVR109. Given that there is an urgent public health need to rapidly develop an effective therapy for COVID-19, we are collaborating with BCM to expeditiously provide the requested information to the FDA. While there can be no assurance regarding timing, we anticipate BCM will initiate a proof-of-concept trial in the second half of 2020, with top-line data expected in 2021.

ALVR107 is an allogeneic, off-the-shelf VST therapy designed to target hepatitis B, or HBV, infected cells and treat chronic HBV. We plan to submit an IND for ALVR107 for the treatment of HBV in the second half of 2021.

ALVR108 is an allogeneic, off-the-shelf VST therapy designed to treat human herpesvirus-8, or HHV8-associated diseases, including Kaposi's sarcoma, or KS, primary effusion lymphoma, or PEL, and multicentric Castlemans's disease, or MCD. We plan to submit an IND for ALVR108 for the treatment of HHV-8 in the second half of 2021.

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

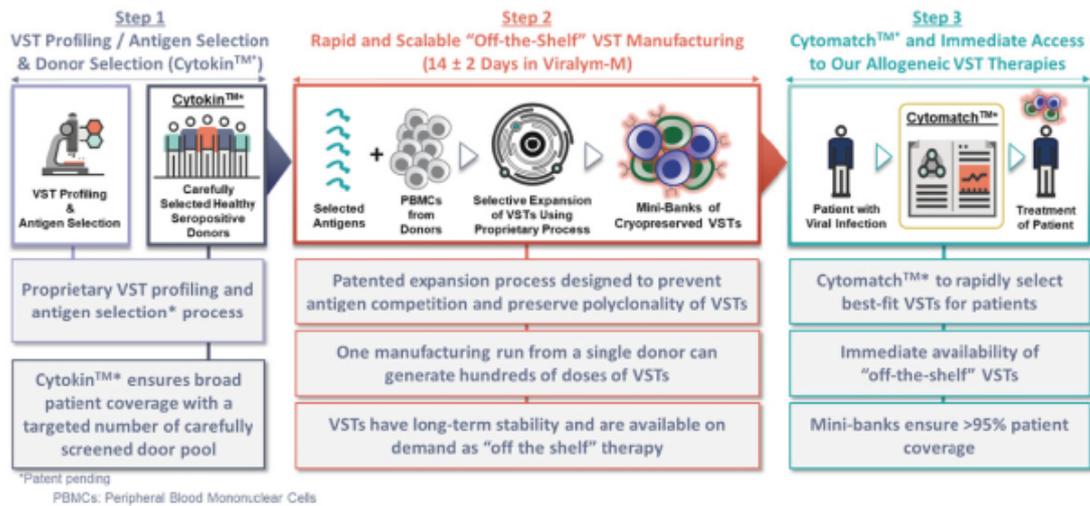
Our immunotherapy approach, as depicted in the figure below, utilizes the adoptive transfer of banked, off-the-shelf VSTs to restore virus-specific immunity in patients at risk from the life-threatening consequences of T cell deficiencies.



Our VSTs are generated from a panel of healthy, third-party blood donors that express a diverse array of human leukocyte antigen, or HLA, allele subtypes. Collectively, these VSTs, which 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. Our off-the-shelf VSTs are partially matched to the patient's HLA subtype allowing them to recognize and selectively kill virus-infected cells while leaving non-virus-infected host cells intact, thereby minimizing the risk of graft-versus-host disease, or GVHD. These VSTs can be stored in a cryopreserved state and as a result, supplied rapidly and globally as an off-the-shelf therapy for patients suffering from, or at risk for contracting, one or more 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
- Cytokin™, our selection algorithm to identify healthy donors from whom to generate VSTs that provide coverage to over 95% of patients in our targeted populations
- Methods of rapidly and selectively expanding polyclonal VSTs *ex vivo*
- Cytomatch™ algorithm to choose the appropriate partially HLA-matched off-the-shelf VST therapy to deliver to each patient



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.

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 by 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.** We believe that Viralym-M, which targets five viral pathogens that cause severe and life-threatening diseases, will transform the care of transplant patients and others at high risk of opportunistic viral infections. Our planned clinical trials include a Phase 3 pivotal trial to assess Viralym-M for the treatment of patients with virus-associated HC and additional Phase 3 pivotal and Phase 2 proof-of-concept prevention and treatment trials.
- **Capitalize on our allogeneic VST platform to advance four additional highly innovative therapies targeting seven life-threatening viruses.** ALVR106 targets four devastating respiratory viruses that each represent a major public health problem. We plan to initially assess ALVR106 for the treatment of HSCT patients suffering from severe respiratory viral infections, and thereafter seek to extend to other high-risk patient populations, such as immunocompromised cancer patients, the very young and the elderly. ALVR109 is an allogeneic, off-the-shelf VST therapy designed to arrest the progression of COVID-19 by eradicating SARS-CoV-2 virus-infected cells. 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 rapidly develop novel therapies for existing and emergent life-threatening viral infections and serve the large number of patients with devastating viral diseases.

- **Leverage our differentiated, proprietary and versatile process to rapidly and efficiently manufacture our VST therapy candidates.** To efficiently build our global supply chain to serve a growing number of patients that could benefit from our allogeneic, off-the-shelf VST therapy candidates, we will leverage Cytokin™ and Cytomatch™, our proprietary algorithms for donor selection and cell line matching, as well as the cell therapy expertise and state-of-the-art facility of ElevateBio to expand internal manufacturing capabilities.
- **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.

Commercial Opportunity

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.

We intend to commercialize our highly innovative off-the-shelf VST therapies globally to serve a large number of patients suffering from the devastating consequences of viral diseases with increasing cost burden to the healthcare system. 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. Many of these transplant centers will have participated in Viralym-M and ALVR106 clinical trials and will have significant experience with our investigational VSTs, which we believe 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 intend to expand our global commercial capabilities.

Our Team

We have a world-class management team, board of directors and scientific advisors with significant experience in virology, cell therapy and progressing product candidates from early stage discovery to clinical trials, regulatory approval and commercialization. Cumulatively, our leadership team has developed and commercialized over 30 products worldwide.

We are led by David Hallal, Chief Executive Officer, a 30-year veteran in the biopharmaceutical industry who previously served as Chief Executive Officer, Chief Operating Officer and Chief Commercial Officer of Alexion Pharmaceuticals. Vikas Sinha, our President and Chief Financial Officer, has over 25 years of experience in the biopharmaceuticals industry and previously served as the Chief Financial Officer of Alexion Pharmaceuticals. Our leadership team also includes co-founder Ann Leen, PhD, Chief Scientific Officer and a Professor in the Department of Pediatrics at the Center of Cell and Gene Therapy at Baylor College of Medicine, Jeroen van Beek, PhD, Chief Commercial Officer, who previously held multiple senior commercial roles at Alexion Pharmaceuticals, Pfizer and Tricida, and Agustin Melian, MD, Chief Medical Officer, who previously held multiple senior clinical roles at Merck and Alexion.

Our Private Financings

To date, we have raised \$156.9 million in aggregate gross proceeds through private financings. Our investors include ElevateBio, Fidelity, Gilead, F2 Ventures, Redmile Group, Invus, EcoR1 Capital and Samsara Biocapital.

Risks Associated with Our Business

Our ability to execute on our business strategy is subject to a number of risks, which are discussed more fully in the section of this prospectus entitled “Risk Factors.” You should carefully consider these risks before making an investment in our common stock. These risks include, among others, the following:

- We have incurred net losses in every period since our inception and anticipate that we will incur significant losses for the foreseeable future.
- We have a limited operating history and face significant challenges and expense as we build our capabilities.
- We are early in our development efforts and only a small number of our product candidates are in clinical development.
- Our single- and multi-VST cell therapy product candidates represent new therapeutic approaches, which makes it difficult to predict the time and cost of product candidate development and obtaining regulatory approval.
- We are heavily reliant on our licensing partners, including BCM, for access to key technology for our product candidates and for the development of certain of our product candidates, including Viralym-M, ALVR106 and ALVR109.
- Our product candidates may cause undesirable side effects or have other properties, our clinical trials may fail to demonstrate the safety and efficacy of any of our product candidates, and we may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.
- Delays in process performance qualification to validate our drug product manufacturing process could delay regulatory approvals, our development plans and thereby limit our ability to generate revenues.
- We face substantial competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.
- We rely and will continue to rely 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. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to conduct our clinical trials on the timelines we expect, and may not be able to obtain regulatory approval of or commercialize our product candidates.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- Certain of our directors and officers may have actual or potential conflicts of interest because of their positions with ElevateBio.
- We will need substantial additional financing to develop our products and implement our operating plans. If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our product candidates.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.
- Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Corporate Information

We were formed in August 2013 under the laws of the state of Delaware under the name AdCyte LLC. In July 2014, we changed our name to ViraCyte LLC. In September 2018, we converted from a Delaware limited liability company to a Delaware corporation and changed our name to ViraCyte, Inc. In May 2019, we changed our name to AlloVir, Inc. Our principal executive offices are located at 139 Main Street, Suite 500, Cambridge, MA 02142, and our phone number is 617-433-2605. We have three wholly-owned subsidiaries, AlloVir International Designated Activity Company, AlloVir Securities Corporation and AlloVir Italia S.R.L., each of which was formed in 2019. Our website address is <https://www.AlloVir.com>. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus.

In September 2018, we entered into a redeemable preferred stock redemption agreement, or Redemption Agreement, to redeem shares of our Series A1 convertible preferred stock held by certain investors. Pursuant to the Redemption Agreement, for a period of 20 years from the date of the first commercial sale of Viralym-M by us, we are obligated to make earnout payments to such investors on at least an annual basis. The earnout payments will be 10% of our net sales of Viralym-M, which number will be reduced to a high single-digit percentage if certain events occur.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For so long as we remain an emerging growth company, we are permitted and intend to rely on certain exemptions from various public company reporting requirements, including the option to present only two years of audited financial statements and only two years of related “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus, not being required to have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments not previously approved. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock.

We may take advantage of these provisions until the earlier to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of the closing of this offering, (b) in which we have total annual gross revenues of at least \$1.07 billion or (c) in which we are deemed to be a “large accelerated filer,” under the rules of the U.S. Securities and Exchange Commission, or SEC, which means the market value of our equity securities that is held by non-affiliates exceeds \$700 million as of the prior June 30th, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

In addition, the JOBS Act provides that 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. We have irrevocably elected to take advantage of this extended transition period 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 private 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.

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We are also a “smaller reporting company,” meaning that the market value of our stock held by non-affiliates plus the proposed aggregate amount of gross proceeds to us as a result of this offering 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 after this offering 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.

THE OFFERING

Common stock offered by us	16,250,000 shares
Option to purchase additional shares	We have granted a 30-day option to the underwriters to purchase up to an aggregate of 2,437,500 additional shares of common stock.
Common stock to be outstanding immediately after this offering	62,669,373 shares (or 65,106,873 shares if the underwriters exercise their option to purchase additional shares in full)
Use of proceeds	We estimate that we will receive net proceeds from the sale of shares of our common stock in this offering of approximately \$253.9 million, or \$292.4 million if the underwriters exercise their option to purchase additional shares in full, based on the initial public offering price of \$17.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, to fund expenses to advance our lead product candidate, Viralym-M, through its planned Phase 3 clinical trials in immunocompromised patients post allogeneic hematopoietic stem cell transplant, or HSCT, in treatment of three virus-associated complications: hemorrhagic cystitis, or HC, cytomegalovirus, or CMV, and adenovirus, or AdV, to fund expenses to advance Viralym-M through its planned Phase 2 clinical trials in prevention of multi-virus infections in HSCT patients, treatment of BK virus infections in kidney transplant recipients and treatment of CMV infections in solid organ transplant recipients, to fund expenses to advance ALVR through its planned Phase 1/2 clinical trials in HSCT patients and other high risk individuals, to fund expenses to advance ALVR109 through its planned Phase 1/2 clinical trial in SARS-CoV-2 and for working capital and general corporate purposes. For a more complete description of our intended use of the proceeds from this offering, see “Use of Proceeds.”
Directed share program	At our request, the underwriters have reserved 5% of the common stock offered by this prospectus for sale, at the initial public offering price, to certain of our directors, officers and employees. Any reserved shares purchased by our directors and officers will be subject to a 180-day lock-up described under “Underwriters.” The sales will be made at our direction by Fidelity Capital Markets, a division of National Financial Services LLC, an entity affiliated

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	with Fidelity Management & Research Company, or FMR, through a directed share program. The number of shares of common stock available for sale to the general public will be reduced by the number of reserved shares sold to these individuals. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same basis as the other shares of common stock offered by this prospectus. See “Underwriters.”
Risk factors	You should carefully read the “Risk Factors” section of this prospectus for a discussion of factors that you should consider before deciding to invest in our common stock.
Dividend policy	We do not currently pay dividends and we do not anticipate declaring or paying any dividends for the foreseeable future.
Nasdaq Global Select Market symbol	“ALVR”

The number of shares of our common stock to be outstanding after this offering of 62,669,373 shares is based on 6,560,234 shares of our common stock outstanding as of June 30, 2020, which includes 3,722,819 shares of unvested restricted stock, and gives effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 39,859,139 shares of our common stock upon the closing of this offering, and excludes:

- 98,643 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2020 under the 2018 Equity Incentive Plan, or 2018 Plan, at a weighted average exercise price of \$3.01 per share;
- 375,093 shares of common stock reserved for future issuance as of June 30, 2020 under the 2018 Plan, which ceased to be available for issuance at the time that our 2020 Stock Option and Grant Plan, or the 2020 Plan, became effective one day prior to the effectiveness of the registration statement of which this prospectus is a part;
- 611,354 shares of our common stock available for future issuance under our 2020 Employee Stock Purchase Plan which became effective one day prior to the effectiveness of the registration statement of which this prospectus is a part; and
- 8,008,734 shares of our common stock available for future issuance under the 2020 Plan (which includes the grant of stock options and restricted stock units to purchase an aggregate of 2,909,200 shares of our common stock granted upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share), which became effective one day prior to the effectiveness of the registration statement of which this prospectus forms a part.

Unless otherwise indicated, all information in this prospectus reflects or assumes the following:

- the filing of our amended and restated certificate of incorporation effective immediately prior to the closing of this offering;
- a 1-for-1.49020520953831 reverse stock split of our common stock, which was effected on July 22, 2020;

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- the adoption of our amended and restated bylaws, effective upon the closing of this offering;
- the conversion of all outstanding shares of preferred stock into an aggregate of 39,859,139 shares of common stock immediately upon the closing of this offering;
- no exercise of the outstanding options described above; and
- no exercise by the underwriters of their option to purchase up to 2,437,500 additional shares of common stock in this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. We have derived the following summary of our condensed consolidated statements of operations data for the three months ended March 31, 2020 and 2019 and our condensed consolidated balance sheet data as of March 31, 2020 from our unaudited condensed consolidated financial statements appearing at the end of this prospectus. In our opinion, the unaudited condensed consolidated financial statements have been prepared on a basis consistent with our audited consolidated financial statements and contains all adjustments, consisting only of normal and recurring adjustments necessary for a fair presentation of such interim financial statements. We have derived the consolidated statements of operations data for the years ended December 31, 2019 and 2018 from our audited consolidated financial statements appearing at the end of this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and our operating results for the three months ended March 31, 2020 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2020 or any other interim periods.

(in thousands, except share and per share amounts)	Three Months Ended March 31,		Years Ended December 31,	
	2020	2019	2019	2018
Consolidated Statements of Operations Data:				
Revenue	\$ —	\$ 165	\$ 165	\$ 1,135
Operating expenses:				
Research and development	6,839	1,151	16,248	1,700
General and administrative	3,001	1,787	10,618	3,031
Total operating expenses	9,840	2,938	26,866	4,731
Loss from operations	(9,840)	(2,773)	(26,701)	(3,596)
Total other income, net:				
Interest income	457	116	2,065	56
Other income, net	44	133	797	1,110
Net loss	(9,339)	(2,524)	(23,839)	(2,430)
Deemed dividend	—	—	—	(5,726)
Net loss attributable to common stockholders	\$ (9,339)	\$ (2,524)	\$ (23,839)	\$ (8,156)
Net loss per share attributable to common stockholders—basic and diluted ⁽¹⁾	\$ (4.21)	\$ (3.19)	\$ (18.54)	\$ (37.36)
Weighted average common shares outstanding—basic and diluted ⁽¹⁾	2,215,958	792,376	1,285,933	204,431
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited) ⁽¹⁾	\$ (0.22)		\$ (0.64)	
Pro forma weighted average common shares outstanding—basic and diluted (unaudited) ⁽¹⁾	42,075,097		37,098,341	
Comprehensive loss:				
Net loss	\$ (9,339)	\$ (2,524)	\$ (23,839)	\$ (2,430)
Other comprehensive income, net of tax				
Unrealized gain on available-for-sale securities	176	—	68	—
Total other comprehensive income	176	—	68	—
Comprehensive loss	\$ (9,163)	\$ (2,524)	\$ (23,771)	\$ (2,430)

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- (1) Net loss per share attributable to common stockholders and weighted average shares outstanding is presented for the period from September 17, 2018 through December 31, 2018 using a net loss attributable to common stockholders of \$7,637. See Notes 2 and 15 to our audited consolidated financial statements and Note 13 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per share, basic and diluted unaudited pro forma net loss per share and the weighted-average number of shares used in the computation of these per share amounts.

	As of March 31, 2020		
	Actual	Pro Forma(2)	Pro Forma as Adjusted(3)
Consolidated Balance Sheet Data:			
Cash, cash equivalents and short-term investments	\$ 115,734	\$ 115,734	\$ 369,751
Working capital(1)	109,668	109,668	363,581
Total assets	128,690	128,690	382,603
Total liabilities	15,583	15,583	15,583
Convertible preferred stock	173,127	—	—
Accumulated deficit	(64,658)	(64,658)	(64,658)
Total stockholders' (deficit) equity	(60,020)	113,107	367,020

- (1) We define working capital as current assets less current liabilities. See our consolidated financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.
- (2) The pro forma balance sheet data gives effect to (i) the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering and (ii) the conversion of all outstanding shares of our convertible preferred stock into 39,859,139 shares of our common stock immediately upon the closing of this offering.
- (3) The pro forma as adjusted balance sheet data gives effect to (i) the pro forma adjustments set forth above and (ii) the receipt of \$253,912,500 million in net proceeds from our sale of 16,250,000 shares of common stock in this offering based on the initial public offering price of \$17.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our consolidated financial statements and the related notes thereto and the section of this prospectus titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” before you make an investment decision. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and prospects. As a result, the market price of our common stock could decline, and you may lose all or part of your investment in our common stock.

Risks Related to Our Financial Condition and Capital Needs

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 \$23.8 million and \$2.4 million for the years ended December 31, 2019 and 2018, respectively. As of March 31, 2020, we had an accumulated deficit of \$64.7 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;

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- 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 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.

Even if we consummate this offering, 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

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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 \$115.7 million as of March 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 this offering, 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 Our Business and the Clinical Development, Regulatory Review and Approval of Our Product Candidates

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.

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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;

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- 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.

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

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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.

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 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.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. For example, on April 16, 2020, the FDA announced that it was continuing to meet key review program user fee performance goals, approve applications and communicate with applicants.

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However, the FDA noted that it may not be able to sustain its current level of performance indefinitely during the COVID-19 pandemic. 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.

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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.

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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. There can be no assurance that the FDA will lift this clinical hold. Any inability to commence or complete our planned clinical trial of ALVR109 as a result of the clinical hold or otherwise, will delay or terminate our clinical development plans for ALVR109, may require us to incur additional clinical development costs and could impair our ability to ultimately obtain FDA approval for ALVR109. Additionally, 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. Clinical trials may be delayed, suspended or prematurely terminated for a variety of 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;

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- 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

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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.

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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 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. Moreover, patients selected for early clinical trials often include those patients with the most severe symptoms, which may have improved notwithstanding the new 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.

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.

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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

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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 from 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

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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.

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.

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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 Vivalym-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 Vivalym-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

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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

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- 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.

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 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,

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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

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- 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, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or 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 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

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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 will commence 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.

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

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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.

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 Commercialization of Our Product Candidates

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

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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 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.

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

Our business is highly dependent on our lead product candidate, 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,

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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, 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.

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 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended these reductions from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. 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.

Since its enactment, there have been judicial and Congressional challenges to numerous elements of the Affordable Care Act, as well as efforts by both the executive and legislative branches of the federal government to repeal or replace certain aspects of the Affordable Care Act. For example, the President signed Executive Orders designed to delay the implementation of certain provisions of the Affordable Care Act or otherwise circumvent some of the requirements for health insurance mandated by the Affordable Care Act. In addition, the U.S. Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While the U.S. Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act, such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld a District Court ruling that the individual mandate was unconstitutional and remanded the case back to the Texas District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review the case, although it is unclear when a decision will be made or how the Supreme Court will rule.

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 Affordable Care Act. Any other executive, legislative or judicial action to "repeal and replace" all or part of the Affordable Care Act 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 Affordable Care Act 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.

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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. Additionally, in May 2018, the U.S. presidential administration laid out a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. HHS has started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. In January 2019, the HHS Office of Inspector General proposed modifications to U.S. federal healthcare Anti-Kickback Statute safe harbors which, among other things, will affect rebates paid by manufacturers to Medicare Part D plans, the purpose of which is to further reduce the cost of drug products to consumers. In addition, in December 2019, the FDA issued a Draft Guidance document outlining a potential pathway for manufacturers to obtain an additional National Drug Code 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. The regulatory and market implications of the Draft Guidance is unknown at this time, but legislation, regulations or policies allowing the reimportation of drugs, if enacted and implemented, could decrease the price we receive for our products and adversely affect our future revenues and prospects for profitability. Although some of these and other proposals may require additional authorization to become effective, members of Congress and the presidential administration 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 extensive 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.

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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 as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Biologics Price Competition and Innovation Act of 2009, 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.

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

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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.

Risks Related to 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

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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.

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.

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

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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 Our Dependence on Third Parties

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

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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

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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.

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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.

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.

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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 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.

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

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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.

Risks Related to Our Intellectual Property

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

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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.

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

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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

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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.

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

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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

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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 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.

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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.

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.

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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.

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.

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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.

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.

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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.

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.

Risks Related to Our Business, Growth and Industry

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

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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.

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.

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

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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-Embircos, 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, in connection with this offering, we expect to adopt 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 July 1, 2020, we had 21 employees. As our development and commercialization plans and strategies develop, and as we transition into 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;

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- 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.

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

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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

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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 this offering or subsequent shifts in our stock ownership, some of which are outside our control. As of December 31, 2019, we had U.S. federal net operating loss carryforwards of approximately \$7.6 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 This Offering and Ownership of Our Common Stock

There has been no prior public market for our common stock and 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 you to sell your shares of our common stock.

Prior to this offering, there was no public trading market for shares of our common stock. Although our common stock has been approved for listing on The Nasdaq Global Select Market, an active trading market for our shares may never develop or be sustained following this offering. You may not be able to sell your shares quickly or at the market price if trading in shares of our common stock is not active. The initial public offering price for our common stock will be determined through negotiations with the underwriters, and the negotiated price may not be indicative of the market price of the common stock after the offering. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. 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 price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering 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 prospectus, 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;

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- 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. If the market price of our common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment. 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.

Prior to this offering, our executive officers, directors, and 5% stockholders beneficially owned approximately 71.75% of our voting stock as of June 30, 2020, and, assuming the sale by us of 16,250,000 shares of common stock in this offering, based on the initial public offering price of \$17.00 per share, and not accounting for any shares purchased in this offering by certain of our existing stockholders (or their affiliates), we anticipate that same group will hold approximately 53.14% of our outstanding voting stock following this offering (assuming no exercise of the underwriters' option to purchase additional shares), without giving effect to any purchases that certain of these holders may make through our directed share program. Therefore, even after this offering, 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

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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 you may feel are in your best interest as one of our stockholders.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The initial public offering price will be substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$11.14 per share, based on the initial public offering price of \$17.00 per share. Further, investors purchasing common stock in this offering will contribute approximately 62.7% of the total amount invested by stockholders since our inception, but will own only approximately 25.9% of the total number of shares of our common stock outstanding after this offering.

This dilution is due to our investors who purchased shares prior to this offering having paid substantially less when they purchased their shares than the price offered to the public in this offering, and the exercise of stock options granted to our employees. To the extent that outstanding stock options or warrants are exercised, there will be further dilution to new investors. As a result of the dilution to investors purchasing common stock in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will experience immediately after this offering, see the section of this prospectus entitled “Dilution.”

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, including shares of common stock sold in this offering.

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Pursuant to our 2020 Stock Option and Incentive Plan, or 2020 Plan, which became effective one day prior to the effectiveness of the registration statement of which this prospectus is a part, our management is authorized to grant stock options to our employees, directors, and consultants.

Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 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.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our net proceeds in ways that ultimately increase or maintain the value of your investment.

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

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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 this prospectus and 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 the year in which we complete this offering, 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 this offering, (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 this prospectus and 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 will be 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 this offering. 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.

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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.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lockup and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline. Upon the closing of this offering, we will have outstanding a total of 62,669,373 shares of common stock. Of these shares, only the shares of common stock sold in this offering by us, plus any shares sold upon exercise of the underwriters' option to purchase additional shares, will be freely tradable without restriction in the public market immediately following this offering. In connection with this offering, our officers, directors and substantially all of our stockholders have agreed to be subject to a contractual lock-up with the underwriters, which will expire 180 days after the date of this prospectus.

The lock-up agreements contain important exceptions that govern their applicability. Morgan Stanley & Co. LLC, J.P. Morgan Securities LLC and SVB Leerink LLC, however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2020 Plan and our 2020 Employee Stock Purchase Plan, each to be effective upon the effectiveness of the registration statement of which this prospectus forms a part, will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

After this offering, the holders of 39,859,139 shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. See "Description of Capital Stock—Registration Rights." Registration of these shares under the Securities Act would result in such shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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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, which are to become effective upon the closing of this offering, will 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 you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our bylaws to be effective upon the consummation of this offering 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 bylaws that will become effective upon the completion of this offering 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

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(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 that will become effective upon the completion of this offering will 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 this offering, we intend to begin 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.

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We have identified a material weakness in our internal control over financial reporting related to fiscal year 2018. If we are unable to remediate this material weakness, or if we experience additional material weaknesses in the future, we may not be able to accurately or timely report our financial condition or results of operations.

As a public company, we will be subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), the Sarbanes-Oxley Act and the rules and regulations of the applicable listing standards of Nasdaq. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting-related costs and significant management oversight.

In finalizing our financial statements for our initial public offering, we identified a material weakness in our internal control over financial reporting related to the accounting for our conversion from a Delaware LLC to a Delaware Corporation in September 2018. This material weakness contributed to an error in our consolidated financial statements for the year ended December 31, 2018, which resulted in the understatement of fair value associated with the Series A1 Preferred Stock received by certain of the prior LLC members in exchange of their previous membership interests. At the time of the LLC Conversion, we were a private company with limited accounting personnel and other resources to address our internal control over financial reporting and this was considered to be a complex, non-standard transaction. Since September 2018 and in order to remediate this material weakness in our internal control over financial reporting and address the deficiency in our accounting processes, we are establishing more robust accounting policies and procedures, reviews on the adoption of new accounting positions and financial statement disclosures, and selection and engagement of consultants to assist us in determining positions and evaluating new accounting policies. Upon completion of this offering, our convertible preferred stock will be converted into common stock resulting in a less complex capital structure and this will assist with our remediation process. We can give no assurance that material weaknesses in our internal control over financial reporting will not be identified in the future. Further, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

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 will 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.

After the completion of this offering, 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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management. Some of the statements in the sections captioned "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this prospectus contain forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this prospectus include, but are not limited to, statements about:

- the success, cost, timing and potential indications of our product development activities and clinical trials, including the ongoing clinical trials of Viralym-M, ALVR106 and ALVR109;
- the timing of our planned IND submissions to the FDA for our product candidates, including ALVR106, ALVR 109, ALVR107 and ALVR 108;
- 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 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 and ALVR106;

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- the rate and degree of market acceptance of our product candidates, including Viralym-M and ALVR106;
- our ability to obtain and maintain regulatory approval of our product candidates in any of the indications for which we plan to develop them, and any related restrictions, limitations or warnings in the label of any approved product we develop;
- our ability to develop and maintain sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries with respect to our product candidates or our competitors' products and product candidates;
- our reliance on third-party contract manufacturers and the performance of our third-party suppliers and manufacturers to manufacture and supply our product candidates for us;
- the success of competing therapies that are or become available;
- our ability to attract and retain key scientific or management personnel;
- our expectation about the period of time over which our existing capital resources and the net proceeds from this offering will be sufficient to fund our operating expenses and capital expenditures, and our use of the proceeds from this offering;
- 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 addition, you should refer to the "Risk Factors" section of this prospectus for a discussion of other important factors that may cause actual results to differ materially from those expressed or implied by the forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Furthermore, if the forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this prospectus represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

MARKET, INDUSTRY AND OTHER DATA

The market data and certain other statistical information used throughout this prospectus are based on independent industry publications, governmental publications, reports by market research firms or other independent sources that we believe to be reliable sources. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. We are responsible for all of the disclosure contained in this prospectus, and we believe these industry publications and third-party research, surveys and studies are reliable. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section entitled “Risk Factors” and elsewhere in this prospectus. Some data are also based on our good faith estimates.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of 16,250,000 shares of our common stock in this offering will be approximately \$253.9 million, or approximately \$292.4 million if the underwriters exercise their option to purchase additional shares in full, based upon the initial public offering price of \$17.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

We currently expect to use the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, as follows:

- approximately \$98 million to fund expenses to advance our lead product candidate, Viralym-M, through its planned Phase 3 clinical trials in immunocompromised patients post allogeneic hematopoietic stem cell transplant, or HSCT, in treatment of three virus-associated complications: hemorrhagic cystitis, or HC, cytomegalovirus, or CMV, and adenovirus, or AdV;
- approximately \$83 million to fund expenses to advance Viralym-M through its planned Phase 2 clinical trials in prevention of multi-virus infections in HSCT patients, treatment of BK virus infections in kidney transplant recipients and treatment of CMV infections in solid organ transplant recipients;
- approximately \$56 million to fund expenses to advance ALVR106 through its planned Phase 1/2 clinical trials in HSCT patients and other high risk individuals;
- approximately \$33 million to fund expenses to advance ALVR109 through its planned Phase 1/2 clinical trial in SARS-CoV-2; and
- the remainder, if any, for working capital and general corporate purposes.

This expected use of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We may also use a portion of the net proceeds to in-license, acquire or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering. Due to uncertainties inherent in the product development process, it is difficult to estimate the exact amounts of the net proceeds that will be used for any particular purpose. We may use our existing cash, cash equivalents and short-term investments and the future payments, if any, generated from any future collaboration agreements to fund our operations, either of which may alter the amount of net proceeds used for a particular purpose. In addition, the amount, allocation and timing of our actual expenditures will depend upon numerous factors, including the results of our research and development efforts, the timing and success of clinical trials and the timing of regulatory submissions. Accordingly, we will have broad discretion in using these proceeds.

Based on our current plans, we believe our existing cash, cash equivalents and short-term investments, together with the net proceeds from this offering, will be sufficient for us to fund our operating expenses and capital expenditure requirements into 2023. We cannot guarantee that we will be able to raise additional capital on reasonable terms or at all.

Pending their uses, we plan to invest the net proceeds of this offering in short- and immediate- term, interest-bearing obligations, investment-grade instruments, or direct or guaranteed obligations of the U.S. government.

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.

CAPITALIZATION

The following table sets forth our cash, cash equivalents and short-term investments and our capitalization as of March 31, 2020:

- on an actual basis;
- on a pro forma basis to give effect to:
 - the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering;
 - the conversion of all outstanding shares of our convertible preferred stock into 39,859,139 shares of our common stock immediately upon the closing of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 16,250,000 shares of common stock in this offering at the initial public offering price of \$17.00 per share, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read the information in this table together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus.

	March 31, 2020		
	Actual	Pro Forma	Pro Forma As Adjusted
<i>(In thousands, except share and per share data)</i>			
Cash, cash equivalents and short-term investments	\$ 115,734	\$ 115,734	\$ 369,751
Convertible preferred stock (Series A and Series B), \$0.0001 par value; 79,398,350 shares authorized, 39,859,139 issued and outstanding, actual; 10,000,000 authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	\$ 173,127	\$ —	\$ —
Stockholders’ (deficit) equity:			
Common stock, \$0.0001 par value; 90,000,000 shares authorized, 6,559,348 shares issued and 2,392,397 shares outstanding, actual; 90,000,000 shares authorized, 46,418,487 shares issued and outstanding, pro forma; 150,000,000 shares authorized, 62,668,487 shares issued and outstanding, pro forma as adjusted	—	5	7
Additional paid-in capital	4,394	177,516	431,427
Accumulated other comprehensive income	244	244	244
Accumulated deficit	(64,658)	(64,658)	(64,658)
Total stockholders’ (deficit) equity	(60,020)	113,107	367,020
Total capitalization	\$ 113,107	\$ 113,107	\$ 367,020

The table above is based on 6,559,348 shares of common stock outstanding as of March 31, 2020, which includes 4,166,951 shares of unvested restricted stock, and gives effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 39,859,139 shares of our common stock immediately upon the closing of this offering, and excludes:

- 48,315 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2020 under the 2018 Plan at a weighted average exercise price of \$3.01 per share;

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- 426,092 shares of common stock reserved for future issuance as of March 31, 2020 under the 2018 Plan, which ceased to be available for issuance at the time that our 2020 Plan became effective one day prior to the effectiveness of the registration statement of which this prospectus is a part;
- 611,354 shares of our common stock available for future issuance under our 2020 Employee Stock Purchase Plan which became effective one day prior to the effectiveness of the registration statement of which this prospectus is a part; and
- 8,008,734 shares of our common stock available for future issuance under the 2020 Plan (which includes the grant of stock options and restricted stock units to purchase an aggregate of 2,909,200 shares of our common stock granted upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share), which became effective one day prior to the effectiveness of the registration statement of which this prospectus forms a part.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of March 31, 2020 was \$(60.1) million, or \$(9.17) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying values of our convertible preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the number of shares of our common stock outstanding at March 31, 2020.

Our pro forma net tangible book value as of March 31, 2020 was \$113.0 million, or \$2.43 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to:

- the filing and effectiveness of our amended and restated certificate of incorporation immediately prior to the closing of this offering; and
- the conversion of all outstanding shares of our convertible preferred stock into 39,859,139 shares of our common stock immediately upon the closing of this offering.

Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares outstanding as of March 31, 2020, after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of 16,250,000 shares of our common stock in this offering at the initial public offering price of \$17.00 per share, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2020 would have been \$367.0 million, or \$5.86 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$3.43 to existing stockholders and immediate dilution of \$11.14 in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share	\$17.00
Historical net tangible book deficit per share at March 31, 2020, before giving effect to this offering	\$(9.17)
Pro forma increase in historical net tangible book value per share attributable to conversion of all outstanding shares of convertible preferred stock	<u>\$11.60</u>
Pro forma net tangible book value per share as of March 31, 2020, before giving effect to this offering	\$ 2.43
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering	<u>\$ 3.43</u>
Pro forma as adjusted net tangible book value per share after this offering	<u>\$ 5.86</u>
Dilution per share to new investors purchasing common stock in this offering	<u>\$11.14</u>

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The following table summarizes, as of March 31, 2020, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at the initial public offering price of \$17.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	<u>Shares Purchased</u>		<u>Total Consideration</u>		<u>Weighted Average Price Per Share</u>
	<u>Number</u>	<u>Percent</u>	<u>Amount</u>	<u>Percent</u>	
Existing stockholders	46,418,487	74.1%	\$164,353,231	37.3%	\$ 3.54
New investors participating in this offering	16,250,000	25.9	\$276,250,000	62.7	\$ 17.00
Total	<u>62,668,487</u>	<u>100.0%</u>	<u>\$440,603,231</u>	<u>100.0%</u>	

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to 71.3% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing common stock in this offering would be increased to 28.7% of the total number of shares of our common stock outstanding after this offering.

The tables and discussion above are based on 6,559,348 shares of common stock outstanding as of March 31, 2020, which includes 4,166,951 shares of unvested restricted stock, and gives effect to the conversion of all outstanding shares of our preferred stock into an aggregate of 39,859,139 shares of our common stock immediately upon the closing of this offering, and exclude:

- 48,315 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2020 under the 2018 Plan at a weighted average exercise price of \$3.01 per share;
- 426,092 shares of common stock reserved for future issuance as of March 31, 2020 under the 2018 Plan, which ceased to be available for issuance at the time that our 2020 Plan became effective one day prior to the effectiveness of the registration statement of which this prospectus is a part;
- 611,354 shares of our common stock available for future issuance under our 2020 Employee Stock Purchase Plan which became effective one day prior to the effectiveness of the registration statement of which this prospectus is a part; and
- 8,008,734 shares of our common stock available for future issuance under the 2020 Plan (which includes the grant of stock options and restricted stock units to purchase an aggregate of 2,909,200 shares of our common stock granted upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share), which became effective one day prior to the effectiveness of the registration statement of which this prospectus is a part.

To the extent that new stock options are issued, or we issue additional shares of common stock in the future, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED CONSOLIDATED FINANCIAL DATA

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this prospectus. We have derived the following summary of our condensed consolidated statements of operations data for the three months ended March 31, 2020 and 2019 and our condensed consolidated balance sheet data as of March 31, 2020 from our condensed consolidated financial statements appearing at the end of this prospectus. We have derived the consolidated statements of operations data for the years ended December 31, 2019 and 2018 from our audited consolidated financial statements appearing at the end of this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

(in thousands, except share and per share amounts) Consolidated Statements of Operations Data:	Three Months Ended March 31,		Years Ended December 31,	
	2020	2019	2019	2018
Revenue	\$ —	\$ 165	\$ 165	\$ 1,135
Operating expenses:				
Research and development	6,839	1,151	16,248	1,700
General and administrative	3,001	1,787	10,618	3,031
Total operating expenses	9,840	2,938	26,866	4,731
Loss from operations	(9,840)	(2,773)	(26,701)	(3,596)
Total other income, net:				
Interest income	457	116	2,065	56
Other income, net	44	133	797	1,110
Net loss	(9,339)	(2,524)	(23,839)	(2,430)
Deemed dividend	—	—	—	(5,726)
Net loss attributable to common stockholders	\$ (9,339)	\$ (2,524)	\$ (23,839)	\$ (8,156)
Net loss per share attributable to common stockholders—basic and diluted ⁽¹⁾	\$ (4.21)	\$ (3.19)	\$ (18.54)	\$ (37.36)
Weighted average common shares outstanding—basic and diluted ⁽¹⁾	2,215,958	792,376	1,285,932	204,431
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited) ⁽¹⁾	\$ (0.22)		\$ (0.64)	
Pro forma weighted average common shares outstanding—basic and diluted (unaudited) ⁽¹⁾	42,075,097		37,098,341	
Comprehensive loss:				
Net loss	\$ (9,339)	\$ (2,524)	\$ (23,839)	\$ (2,430)
Other comprehensive income, net of tax				
Unrealized gain on available-for-sale securities	176	—	68	—
Total other comprehensive income	176	—	68	—
Comprehensive loss	\$ (9,163)	\$ (2,524)	\$ (23,771)	\$ (2,430)

⁽¹⁾ Net loss per share attributable to common stockholders and weighted average shares outstanding is presented for the period from September 17, 2018 through December 31, 2018 using a net loss attributable to common stockholders of \$7,637. See Notes 2 and 15 to our audited consolidated financial statements and Note 13 to our unaudited condensed consolidated financial statements included elsewhere in this prospectus for a description of how we compute basic and diluted net loss per share and basic and diluted unaudited pro forma net loss per share, and the weighted-average number of shares used in the computation of these per share amounts.

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	<u>March 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u> <u>2018</u>	
		(In thousands)	
Consolidated Balance Sheet Data:			
Cash, cash equivalents and short-term investments	\$ 115,734	\$ 126,077	\$ 24,960
Working capital ⁽¹⁾	109,668	118,207	21,576
Total assets	128,690	139,422	25,319
Total liabilities	15,583	17,798	3,737
Convertible preferred stock	173,127	173,127	52,204
Accumulated deficit	(64,658)	(55,319)	(31,480)
Total stockholders' deficit	(60,020)	(51,503)	(30,622)

⁽¹⁾ We define working capital as current assets less current liabilities. See our consolidated financial statements and related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

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 the "Selected Consolidated Financial Data" section of this prospectus and our consolidated financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, 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 of which has successfully completed a proof-of-concept trial across five viruses and is entering initial pivotal trials for the treatment of virus-associated hemorrhagic cystitis in the fourth quarter of 2020. Our management team has significant experience in successfully advancing products from early stage discovery through commercialization. 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.

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 in 2020 and 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, we anticipate filing an Investigational New Drug, or IND, application with the FDA in the second half of 2020 for our second cell therapy, ALVR106, an allogeneic, off-the-shelf, VST therapy designed to target severe respiratory diseases caused by four respiratory viruses: respiratory syncytial virus, influenza, parainfluenza virus and human metapneumovirus. We plan to initiate a Phase 1/2 clinical study in autologous and allogeneic HSCT patients with respiratory viral diseases in the fourth quarter of 2020. 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. Since our inception, we have funded our operations primarily through equity financings and have received proceeds of approximately \$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 \$9.3 million, \$23.8 million and \$2.4 million for the three months ended March 31, 2020 and the years ended December 31, 2019 and 2018, respectively. As of March 31, 2020 and December 31, 2019, we had an accumulated deficit of

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\$64.7 million and \$55.3 million, respectively. 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.

Furthermore, following the closing of this offering, 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.

As of March 31, 2020, we had cash, cash equivalents and short-term investments of \$115.7 million. We believe that the anticipated net proceeds from this offering, 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. 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

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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.

Additionally, the United States enacted the Coronavirus Aid, Relief and Economic Security Act, or CARES Act. The CARES Act is an approximately \$2 trillion emergency economic stimulus package in response to the COVID-19 pandemic, which among other things contains numerous income tax provisions. Some of these income tax provisions are expected to be effective retroactively for years ending before the date of enactment. We are currently evaluating the impact of the CARES Act on its consolidated financial position, results of operations, and cash flows.

Relationship with ElevateBio

On September 17, 2018, we entered into a Series A2 Preferred Stock Purchase Agreement, or the Series A2 Agreement, with ElevateBio LLC, or ElevateBio, concurrent with the LLC Conversion (see Note 11 to our audited consolidated financial statements appearing elsewhere in this prospectus). 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, ElevateBio acquired an ownership interest (see Note 12 to our audited consolidated financial statements and Note 10 to our unaudited interim condensed consolidated financial statements appearing at the end of this prospectus for further discussion). The Chief Executive Officer, Chief Financial Officer, and other executives of ElevateBio also serve in similar management roles with us.

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.

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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 discovery studies or other services performed. Significant judgment and estimates are made in determining the accrued expense balances at the end of any reporting period.

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

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

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

The successful development of our product candidates is highly uncertain. We plan to 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.

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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.

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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 other government grants based on expenditures that qualify for reimbursement and interest expense 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 Three Months Ended March 31, 2020 and 2019

The following table summarizes our results of operations:

	Three Months Ended March 31,		Change
	2020	2019	
Revenue	\$ —	\$ 165	\$ (165)
Operating expenses:		(in thousands)	
Research and development	6,839	1,151	5,688
General and administrative	3,001	1,787	1,214
Total operating expenses	9,840	2,938	6,902
Loss from operations	(9,840)	(2,773)	(7,067)
Total other income, net:			
Interest income	457	116	341
Other income, net	44	133	(89)
Net loss	<u>\$ (9,339)</u>	<u>\$ (2,524)</u>	<u>\$ (6,815)</u>

Revenue

We recognized no revenue for the three months ended March 31, 2020, while we recognized revenue of \$0.2 million for the three months ended March 31, 2019 under the CPRIT Grant. No revenue was recognized for the three months ended March 31, 2020 as a result of the termination of the CPRIT grant. We received acknowledgment of the termination from CPRIT in January 2020.

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Research and Development Expenses

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

	Three Months Ended March 31,		Change
	2020	2019	
Direct research and development expenses by program:			
Viralym-M	\$2,090	\$ 90	\$2,000
ALVR106	1,473	—	1,473
Discovery	304	2	302
Unallocated research and development expenses:			
Personnel expenses (including stock-based compensation)	2,776	977	1,799
Other expenses	196	82	114
Total research and development expenses	<u>\$6,839</u>	<u>\$1,151</u>	<u>\$5,688</u>

Research and development expenses were \$6.8 million for the three months ended March 31, 2020, compared to \$1.2 million for the three months ended March 31, 2019. The increase of \$5.7 million was primarily due to:

- a \$2.0 million increase in costs related to the development of Viralym-M, our most advanced product candidate, specifically due to the increased activity in outsourcing of manufacturing and the development of clinical trials;
- a \$1.5 million increase in costs related to the development of ALVR106, primarily due to increased costs related to the outsourcing of manufacturing activities and the onboarding of CROs in clinical trials;
- a \$0.3 million increase in costs related to discovery activities as a result of increased efforts toward identifying product candidates;
- a \$1.8 million increase in personnel-related costs, including stock-based compensation expense, primarily due to an increase in headcount and external consultants in support of research activities; and
- a \$0.1 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 \$3.0 million for the three months ended March 31, 2020, compared to \$1.8 million for the three months ended March 31, 2019. The increase of \$1.2 million consisted of an increase of \$0.9 million in payroll and personnel-related costs, including stock-based compensation, primarily due to an increase in headcount and external consultants, a \$0.1 million increase in legal, accounting and professional fees and a \$0.2 million increase in other general and administrative expenses related to costs associated with operating activities and the preparations for becoming a public company.

Total Other Income, Net

Total other income, net was \$0.5 million for the three months ended March 31, 2020, compared to \$0.2 million for the three months ended March 31, 2019. The increase of \$0.3 million is primarily attributable to an increase in interest income related to short-term investments, partially offset by a decrease in other government grant reimbursements.

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Comparison of the Years Ended December 31, 2019 and 2018

The following table summarizes our results of operations:

	Year Ended December 31,		Change
	2019	2018	
	(in thousands)		
Revenue	\$ 165	\$ 1,135	\$ (970)
Operating expenses:			
Research and development	16,248	1,700	14,548
General and administrative	10,618	3,031	7,587
Total operating expenses	26,866	4,731	22,135
Loss from operations	(26,701)	(3,596)	(23,105)
Total other income, net:			
Interest income	2,065	56	2,009
Other income, net	797	1,110	(313)
Net loss	<u>\$ (23,839)</u>	<u>\$ (2,430)</u>	<u>\$ (21,409)</u>

Revenue

We recognized revenue of \$0.2 million for the year ended December 31, 2019, compared to \$1.1 million for the year ended December 31, 2018. The decrease of \$0.9 million was due to a decrease in consideration received from the CPRIT Grant due to a decrease in qualifying expenses on research and development activities for our Phase 2 clinical trial for Viralym-M. In November 2019, we provided CPRIT with written notice of our intent to terminate the grant. We received acknowledgment of the termination from CPRIT in January 2020.

Research and Development Expenses

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

	Year Ended December 31,		Change
	2019	2018	
Product candidates	\$ 8,480	\$ 457	\$ 8,023
Personnel expenses (including stock-based compensation)	7,132	1,243	5,889
Other expenses	636	—	636
Total research and development expenses	<u>\$ 16,248</u>	<u>\$ 1,700</u>	<u>\$14,548</u>

Research and development expenses were \$16.2 million for the year ended December 31, 2019, compared to \$1.7 million for the year ended December 31, 2018. The increase of \$14.5 million was primarily due to:

- an \$8.0 million increase in costs related to the development of Viralym-M and ALVR106 and an increase in costs related to discovery activities as a result of increased efforts toward identifying product candidates, increased costs related to the outsourcing of manufacturing activities and the onboarding of CROs in clinical trials;
- a \$5.9 million increase in personnel-related costs, including stock-based compensation expense, primarily due to an increase in headcount and increasing the use of external consultants in support of research activities; and
- a \$0.6 million increase in other research and development expenses, including facilities, rent, travel and insurance driven by an increase in headcount.

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General and Administrative Expenses

General and administrative expenses were \$10.6 million for the year ended December 31, 2019, compared to \$3.0 million for the year ended December 31, 2018. The increase of \$7.6 million consisted of an increase of \$5.8 million in payroll and personnel-related costs, including stock-based compensation, primarily due to an increase in headcount, a \$1.3 million increase in legal, accounting and professional fees and a \$0.5 million increase in other general and administrative expenses related to costs associated with operating activities and the preparations for becoming a public company.

Total Other Income, Net

Total other income, net was \$2.9 million for the year ended December 31, 2019, compared to \$1.2 million for the year ended December 31, 2018. The increase of \$1.7 million is primarily attributable to an increase in interest income related to the short-term investments purchased in 2019, partially offset by interest expense related to the CPRIT grant termination and a decrease in other government grant reimbursements as compared to 2018.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2020, we have funded our operations primarily through equity financings and have received proceeds of approximately \$156.3 million, net of issuance costs of \$0.6 million, from the sale of our preferred stock. As of March 31, 2020, we had \$115.7 million of cash, cash equivalents and short-term investments.

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

As of March 31, 2020, our cash, cash equivalents and short-term investments were \$115.7 million. We believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital expenditure requirements into . 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, upon the completion of this offering, 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.

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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.

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Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Three Months Ended		Year Ended	
	March 31,	2019	December 31,	2018
	2020		2019	2018
	(in thousands)			
Net cash (used in) provided by operating activities	\$ (10,543)	\$ (1,977)	\$ (20,155)	\$ 1,943
Net cash provided by (used in) investing activities	13,839	—	(64,644)	—
Net cash (used in) provided by financing activities	—	(31)	120,923	22,872
Net increase (decrease) in cash, cash equivalents and restricted cash	<u>\$ 3,296</u>	<u>\$ (2,008)</u>	<u>\$ 36,124</u>	<u>\$ 24,815</u>

Operating Activities

Net cash used in operating activities was \$10.5 million for the three months ended March 31, 2020, reflecting a net loss of \$9.3 million and a net change of \$1.8 million in our net operating assets, partially offset by non-cash charges of \$0.6 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 a decrease of \$1.5 million in accounts payable and accrued expenses, and an increase of \$0.3 million for unbilled grants receivable, accrued interest and prepaid expenses and other current assets.

Net cash used in operating activities was \$2.0 million for the three months ended March 31, 2019, reflecting a net loss of \$2.5 million, offset by a net change of \$0.3 million in our net operating assets and non-cash charges of \$0.2 million. The non-cash charge consists of stock compensation expense. The change in our net operating assets and liabilities was primarily due to an increase of \$0.8 million in accounts payable and accrued expenses, partially offset by an increase of \$0.4 million in unbilled grants receivable and prepaid expenses and other current assets and a \$0.2 million decrease in deferred grant revenue.

The \$8.6 million increase in cash used in operating activities for the three months ended March 31, 2020 compared to the three months ended March 31, 2019 is primarily due to an increase in research and development expenses and general and administrative expenses as a result of our increased efforts towards identifying product candidates and advancing the development of Viralym-M and ALVR106 including increased personnel costs related to our increased headcount.

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.

Net cash provided by operating activities was \$1.9 million for the year ended December 31, 2018, reflecting a net loss of \$2.4 million, offset by a net change of \$3.4 million in our net operating assets and non-cash charges of \$1.0 million. The non-cash charge consists of stock-based compensation expense. The change in our net operating assets and liabilities was primarily due to an increase of \$3.3 million in deferred grant revenue and accounts payable and accrued expenses.

The \$22.1 million increase in cash used in operating activities for the year ended December 31, 2019 compared to December 31, 2018 is primarily due to an increase in research and development expenses and

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general and administrative expenses as a result of our increased efforts towards identifying product candidates and advancing the development of Viralym-M and ALVR106 and personnel related costs.

Investing Activities

Net cash provided by investing activities was \$13.8 million for the three months ended March 31, 2020. We had no investing activities for the three months ended March 31, 2019. Net cash provided by investing activities for the three months ended March 31, 2020 was primarily due to investment maturities of \$35.0 million, partially offset by the purchase of investments of \$21.2 million.

Net cash used in investing activities was \$64.6 million for the year ended December 31, 2019. We had no investing activities for the year ended December 31, 2018. 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. We invest in lower risk, government issued debt securities or U.S. treasury securities as a means of capital preservation.

Financing Activities

We had no financing activities for the three months ended March 31, 2020. Net cash used in financing activities was \$31,000 for the three months ended March 31, 2019. Net cash used in financing activities for the for the three months ended March 31, 2019 was primarily due to issuance costs incurred prior to the issuance of Series B Preferred Stock in May 2019.

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. Net cash provided by financing activities was \$22.9 million for the year ended December 31, 2018. The change was primarily due to net proceeds of \$32.9 million from the issuance of Series A2 Preferred Stock and A4 Preferred Stock, partially offset by a decrease of \$10.0 million related to the redemption of Redeemable Preferred Stock.

Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2019 (in thousands):

	Payments Due By Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Purchase obligations	\$10,666	\$ 2,665	\$ 6,096	\$ 1,905	\$ —
Operating lease obligations	12,900	3,600	7,200	2,100	—
Total	<u>\$23,566</u>	<u>\$ 6,265</u>	<u>\$13,296</u>	<u>\$ 4,005</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.

Collaboration and Research 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 April 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. The amendment establishes

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royalties and milestones for the added pre-clinical products; on the SARS-CoV-2 product, we are obligated to pay BCM \$3.0 million upon the FDA's approval of a licensed product for the prevention and treatment of COVID-19 as well as sales-based milestone payments of up to \$37.5 million in the aggregate from the commercial sale of such licensed product. These payments are not included in the table above as the timing of such payments is not known and has not yet been deemed probable.

Redeemable Preferred Stock Redemption Agreement

In September 2018, we entered into a redeemable preferred stock redemption agreement, or Redemption Agreement, to redeem shares of our Series A1 convertible preferred stock held by certain investors. Pursuant to the Redemption Agreement, for a period of 20 years from the date of the first commercial sale of Viralym-M by us, we are obligated to make earnout payments to such investors on at least an annual basis. The earnout payments will be 10% of our net sales of Viralym-M, which number will be reduced to a high single-digit percentage if certain events occur. Specifically, royalties due to third parties for the sale of Viralym-M are subtracted from the earnout payments due to the investors. Further, if the investors receive at least \$50,000,000 in earnout payments from us during the three-year period commencing after the first commercial sale of Viralym-M, the earnout payment percentage will be reduced to a high single-digit percentage. These payments are not included in the table above as the amounts and timing of such payments are not known.

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—License Agreements" as well as Note 8 to our audited consolidated financial statements and Note 7 to our unaudited interim condensed consolidated financial statements appearing elsewhere in this prospectus 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 prospectus, 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.

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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 measure stock-based compensation based on the grant date fair value of the stock-based awards and recognize stock-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period of the respective award. For non-employee awards, compensation expense is recognized as the services are provided, which is generally ratably over the vesting period. 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. We recognize stock-based compensation expense on a straight-line basis over the vesting period, which is also the requisite service period. Forfeitures are accounted for as they occur.

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 fair value of each restricted common stock award is 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

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consisting of an option-pricing method and a zero-value scenario. As there is currently no public market for our common stock, we determined 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. 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.

As there has been no public market for our common stock to date, 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. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company’s securities changes. Under this method, the common stock have value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. The hybrid method is a probability-weighted expected return method, PWERM, where the equity value in one or more scenarios is calculated using an OPM. The PWERM is a scenario-based methodology that estimates the fair value of common stock based upon an analysis of future values for the company, assuming various outcomes. The common stock value is based on the probability-weighted present value of expected future investment returns considering each of the possible outcomes available as well as the rights of each class of stock. The future value of the common stock under each outcome is discounted back to the valuation date at an appropriate risk-adjusted discount rate and probability weighted to arrive at an indication of value for the common stock.

In the application of these various methods, our contemporaneous valuations over time have included a decreasing lack of marketability discount assumption and an increasing probability of an IPO exit assumption based on our improved financial position as a result of our Series A and Series B financings, increased valuation thresholds at IPO pursuant to Series A and Series B financings and increased probability of advancing towards an IPO scenario, as well as progress made on our Viralym-M which has completed Phase 2 trials and is anticipated to enter Phase 3 clinical trials in the third quarter of 2020.

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;

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- 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. These judgments and estimates include assumptions regarding our future operating performance, the stage of development of our product candidates, the timing of a potential IPO or other liquidity event and the determination of the appropriate valuation methodology at each valuation date. 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 completion of this offering, the fair value of our common stock will be determined based on the quoted market price of our common stock.

Options granted

The following table sets forth by grant date, the number of shares underlying options granted, the per share exercise price of options, the fair value of per common share on each grant date, and the per share estimated fair value of the options granted since January 1, 2019.

<u>Grant Date</u>	<u>Number of Common Shares Subject to Options Granted</u>	<u>Exercise Price per Common Share⁽¹⁾</u>	<u>Estimated per Share Fair Value of Options⁽²⁾</u>	<u>Estimated Fair Value per Common Share on Grant Date</u>	<u>Type</u>
October 16, 2019	44,960	\$ 3.01	\$ 2.17	\$ 3.01	Non-Qualified Stock Options
February 17, 2020	3,355	\$ 3.01	\$ 2.17	\$ 3.01	Incentive Stock Options
May 18, 2020	50,328	\$ 4.60	\$ 3.38	\$ 4.60	Incentive Stock Options

(1) The exercise price per common share represents the fair value of our common shares on the date of grant, as determined by our board of directors.

(2) The estimated per share fair value of options reflects the weighted average fair value of options granted on each grant date, determined using the Black-Scholes option-pricing model.

In July 2020, our board of directors approved option grants to purchase an aggregate of 2,909,200 shares of our common stock to certain of our directors, officers and employees contingent and effective upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share in this offering.

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

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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 plus the proposed aggregate amount of gross proceeds to us as a result of this offering 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 after this offering 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

As of March 31, 2020 and December 31, 2019, 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 condensed consolidated financial statements appearing at the end of this prospectus.

Qualitative and Quantitative Disclosures about Market Risk

We are exposed to certain market risks in the ordinary course of our business, which are principally limited to interest rate fluctuations and foreign currency exchange rate fluctuations. We maintain significant amounts of cash, cash equivalents and short-term investments that are in excess of federally insured limits in various currencies, placed with one or more financial institutions for varying periods according to expected liquidity requirements.

Interest Rate Risk

As of March 31, 2020 and December 31, 2019, we held cash, cash equivalents and short-term investments of \$115.7 million and \$126.1 million, respectively. Our exposure to interest rate sensitivity is impacted by changes in the underlying U.S. and European bank interest rates. Our surplus cash has been invested in interest-bearing savings, money market funds and U.S. Treasury securities. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

As of March 31, 2020 and December 31, 2019, we had no debt outstanding, and therefore are not subject to interest rate risk related to debt.

Foreign Currency Exchange Risk

Our reporting currency is the U.S. dollar, or USD. Our 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 statements of members' interests, preferred stock and changes in members' and stockholders' deficit as a component of accumulated other comprehensive income (loss). Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the functional currency are included in other income (expense), net in the consolidated statements of operations and comprehensive loss as incurred.

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

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 of which has successfully completed a proof-of-concept trial across five viruses and is entering initial pivotal trials for the treatment of virus-associated hemorrhagic cystitis in the fourth quarter of 2020.

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 initiate a total of three Phase 3 pivotal and three Phase 2 proof-of-concept trials in 2020 and 2021 for the treatment and prevention of life-threatening viral diseases in pediatric and/or adult patients, each representing a potential meaningful commercial opportunity.

Based on the data generated from our Phase 2 proof-of-concept trial and the critical medical need, Viralym-M has been granted PRiority 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. To date, Viralym-M is one of only 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. We expect to have three cell therapies in the clinic in 2020.

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

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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 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. We anticipate filing an Investigational New Drug, or IND, application with the FDA for ALVR106 in the second half of 2020.
- 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 Collage of Medicine, or BCM, submitted an IND application with the FDA for ALVR109 in June 2020. In July 2020, the IND was placed on clinical hold for safety concerns related to the quality of ancillary reagents unique to ALVR109. Given that there is an urgent public health need to rapidly develop an effective therapy for COVID-19, we are collaborating with BCM to expeditiously provide the requested information to the FDA. While there can be no assurance regarding timing, we anticipate BCM will initiate a proof-of-concept trial in the second half of 2020, with top-line data expected in 2021.
- We are also advancing ALVR107 to 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 submit an IND for ALVR107 for the treatment of HBV 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

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proof-of-concept trials using Viralym-M for the treatment and prevention of severe and life-threatening viral diseases in pediatric and/or adult patients in 2020 and 2021.

- **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 anticipate submitting an IND with the FDA for ALVR106 in the second half 2020 and initiating our Phase 1/2 clinical trial in HSCT patients and other high risk individuals such as immunocompromised cancer patients, the elderly and very young with immature immune systems in the fourth quarter of 2020.
- **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. In its capacity as trial sponsor, BCM submitted an IND application with the FDA for ALVR109 in June 2020. While this IND is currently on clinical hold, we are working with BCM to expeditiously resolve the FDA information requests.
- **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 submit an IND 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 submit an IND 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 plan to initiate additional Phase 3 pivotal and Phase 2 proof-of-concept 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 are developing 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 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.

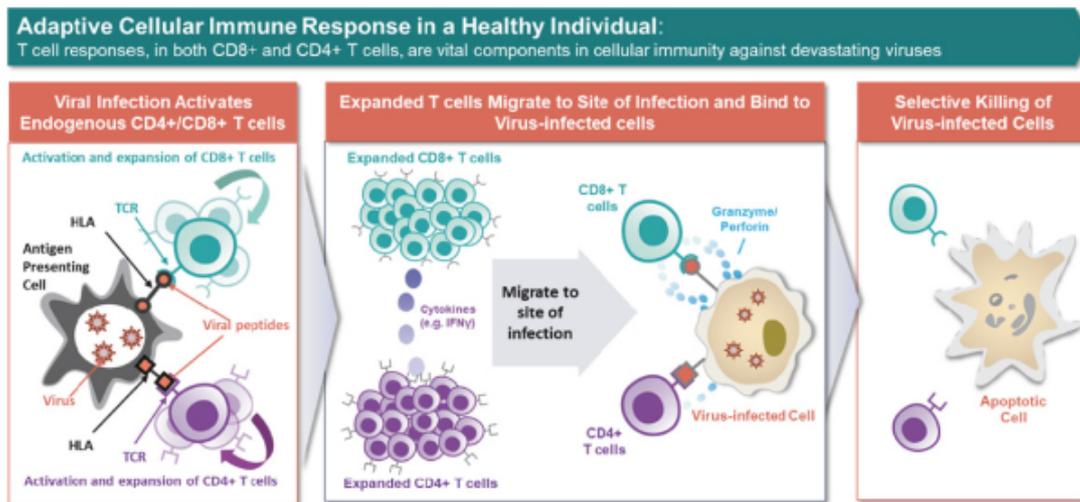


Figure 1. T cells play a central role in response to viral infection

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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.

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In approximately 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.

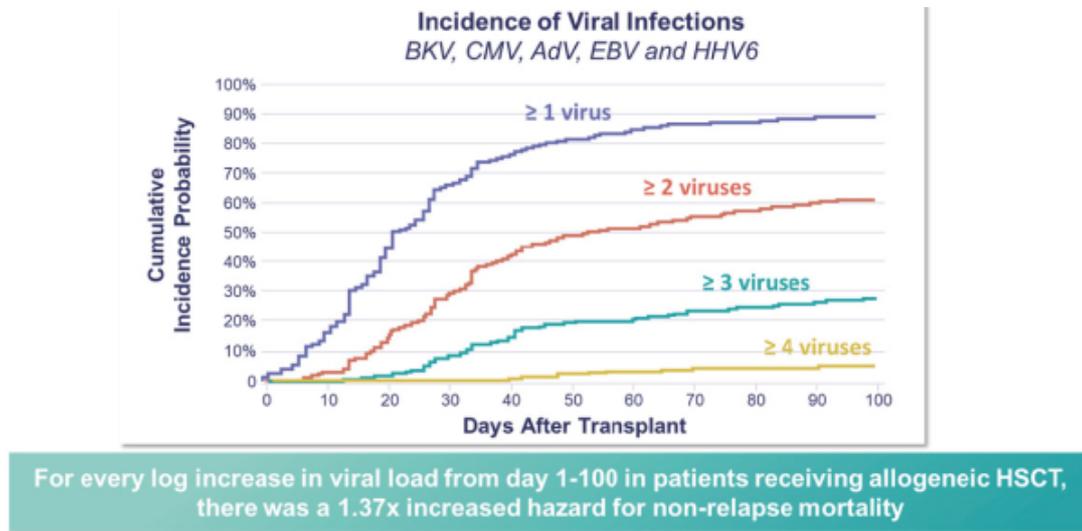
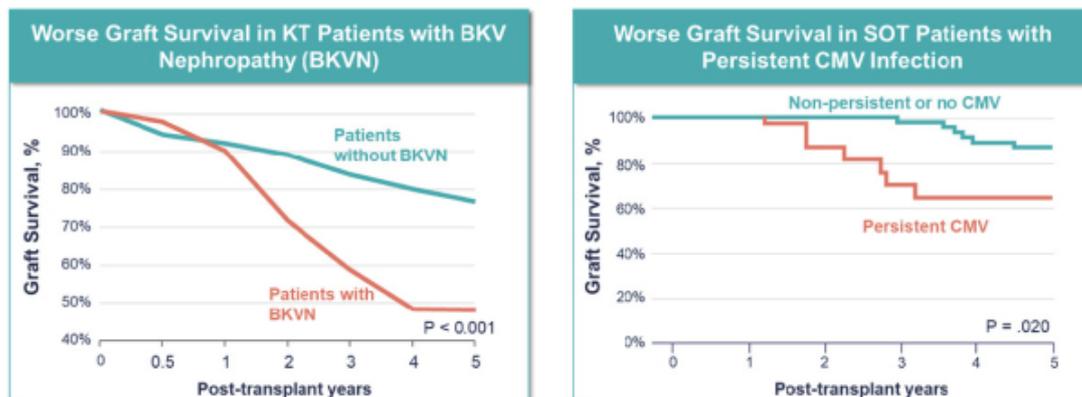


Figure 2. Approximately 90% of patients undergoing allogeneic HSCT have at least one viral infection and 62% have more than one.

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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

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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.

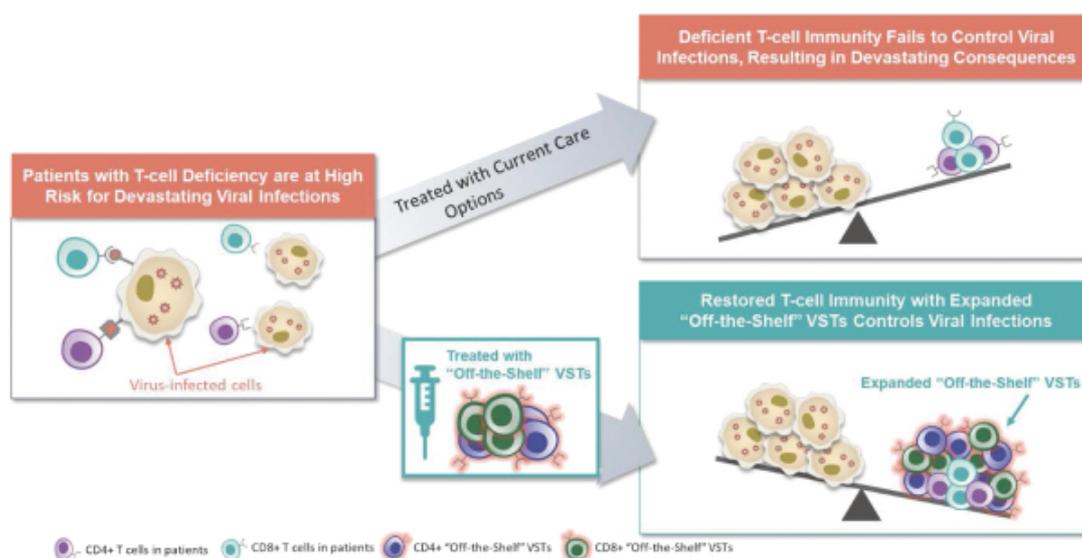


Figure 3: Adoptive transfer of off-the-shelf VSTs kill virus-infected cells and restore virus-specific T cell immunity

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.

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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.

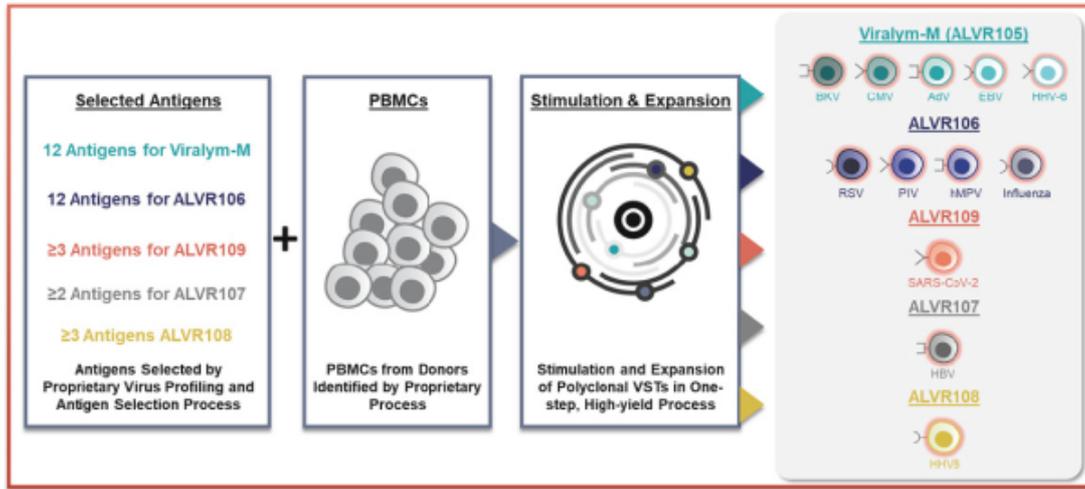


Figure 4. Allovir’s versatile off-the-shelf VST manufacturing platform

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, Cytokin™; (2) rapid and scalable off-the-shelf VST manufacturing; and (3) our proprietary, customized VST cell line selection process, Cytomatch™, which allows for immediate patient access to our allogeneic VST therapy.

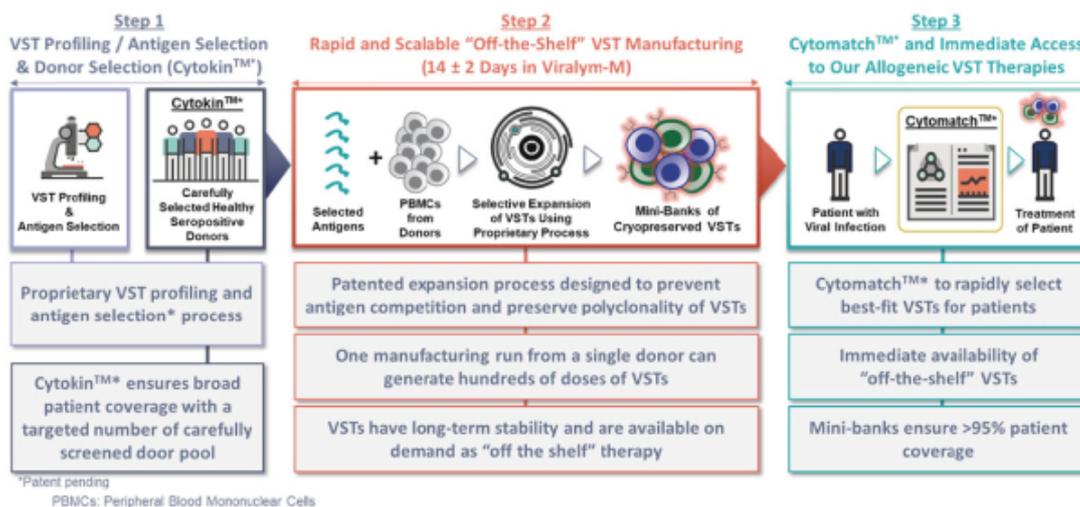


Figure 5. Key advantages of AlloVir’s patented, highly efficient and industrialized VST platform

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

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

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

Donor Selection—Cytokin™

We next apply our Cytokin™ algorithm, as depicted in the figure below, to select the optimal combination of donors from whom to generate VSTs. Cytokin™ compares the HLA types of our targeted patient population with a pool of diverse healthy, eligible seropositive donors and identifies a subset of donors, or a mini-bank, that collectively provide 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.

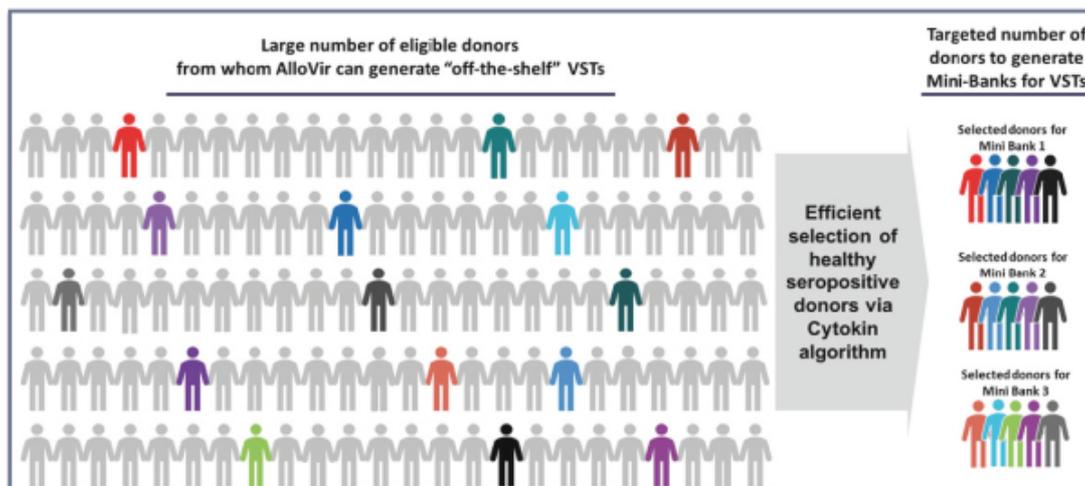


Figure 6. Implementing the Cytokin™ algorithm to efficiently select donors from whom to generate mini-banks of VSTs

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

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

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

Our ability to generate allogeneic, off-the-shelf VSTs in a single-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 by 2021.

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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.

THERAPY CANDIDATE	TARGET INDICATION	TARGET POPULATION	PRECLINICAL	POC TRIAL (Phase 1b/2)	PIVOTAL TRIAL (Phase 3)
Viralym-M (ALVR105) Multi-VSTs targeting BKV, CMV, AdV, EBV, and HHV-8	Treatment of Virus-Associated Hemorrhagic Cystitis	Allo-HSCT	████████████████████	████████████████████	
	Treatment of CMV	Allo-HSCT	████████████████████	████████████████████	
	Treatment of AdV	Allo-HSCT	████████████████████	████████████████████	
	Prevention of BKV, CMV, AdV, EBV, HHV-8 and JCV	Allo-HSCT	████████████████		
	Treatment of BKV	KT	████████████████		
	Treatment of CMV	SOT	████████████████		
ALVR106 Multi-VSTs targeting RSV, Influenza, PIV and hMPV	Treatment of RSV, Influenza, PIV, and hMPV	Allo-/Auto-HSCT	████████████████████		
	Treatment of RSV, Influenza, PIV, and hMPV	High-risk general population	████████████████████		
ALVR109 Single-VSTs targeting SARS-CoV-2	Treatment of COVID-19	High-risk general population	████████████████████		
ALVR107 Single-VSTs targeting HBV	Treatment of HBV	Patients with chronic HBV	████████████████		
ALVR108 Single-VSTs targeting HHV-8	Treatment of HHV-8	Patients with KS, MCD or PEL	████████████████		

POC: Proof-of-concept; Allo-HSCT: Allogeneic HSCT; Auto-HSCT: Autologous HSCT; KT: Kidney Transplant; SOT: Solid Organ Transplant; KS: Kaposi Sarcoma; MCD: Multicentric Castlemans Disease; PEL: Primary Effusion Lymphoma

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)

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- 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. To date, Viralym-M is one of only 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, which can be as long as 180 days, 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.

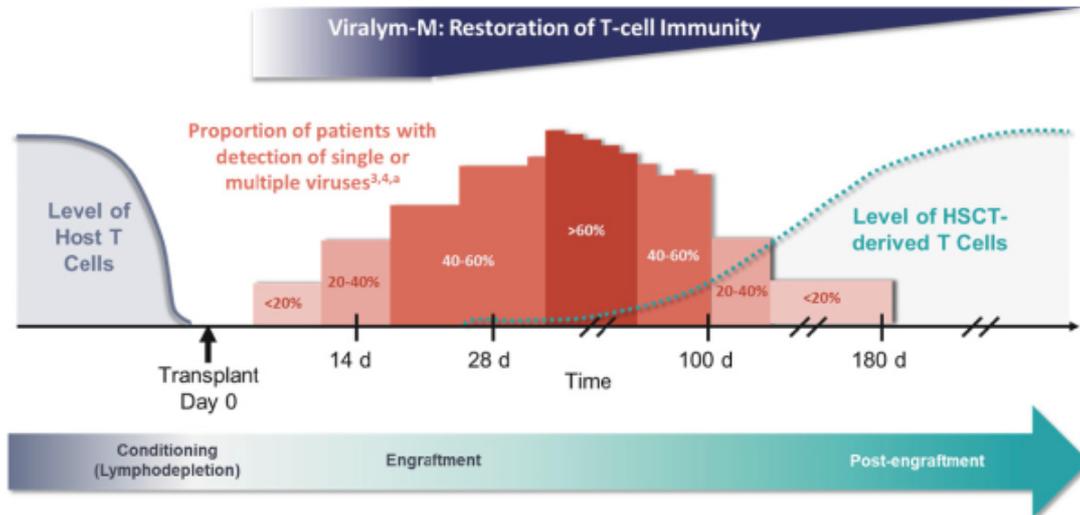


Figure 7. *Viralym-M* is designed to treat and prevent viral diseases until the patient’s own immune system recovers

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.

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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.

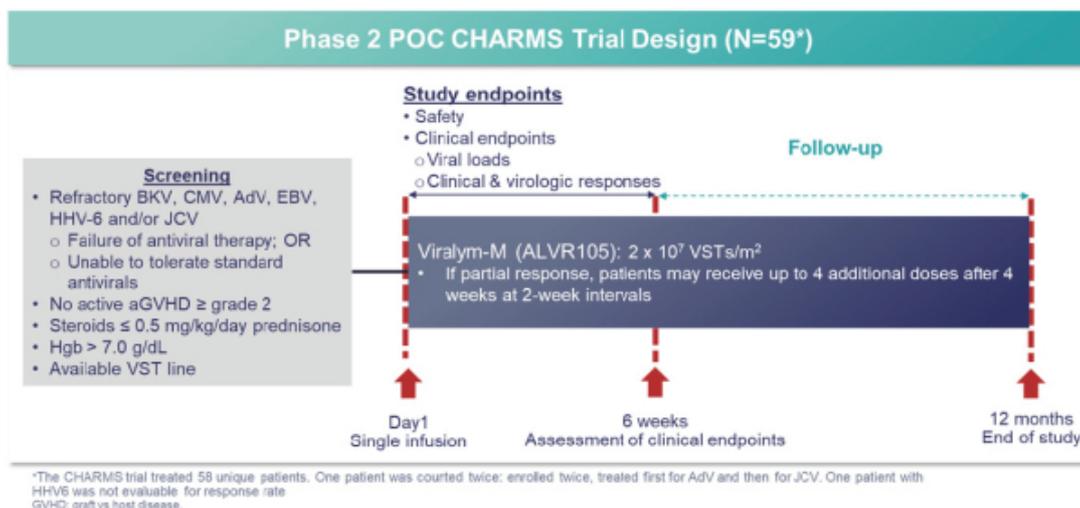


Figure 8. CHARMS—Phase 2, proof-of-concept, open label trial design

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.

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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

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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.

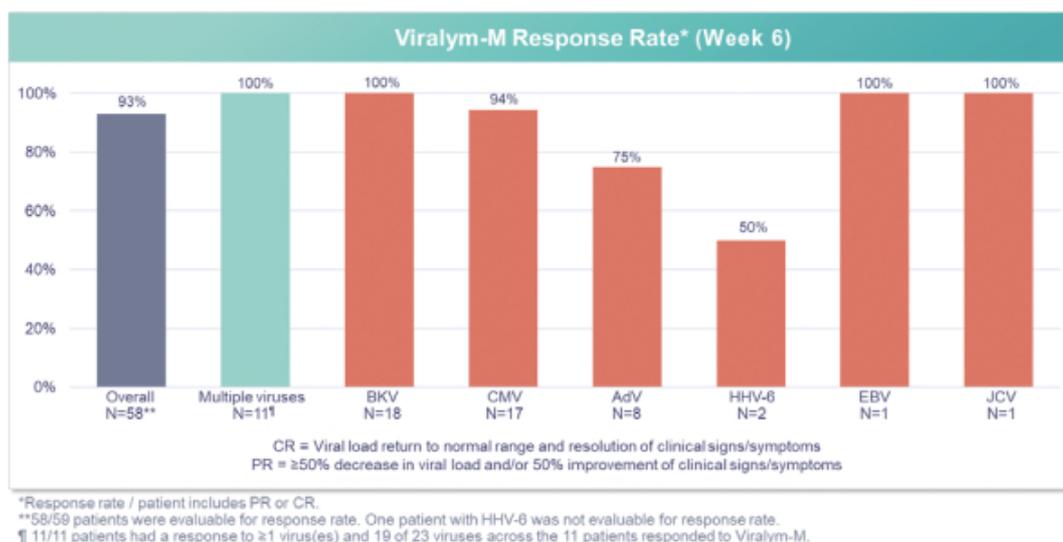


Figure 9. *Viralym-M Phase 2 proof-of-concept trial (CHARMS): 93% overall response rate in patients with viral disease by 6 weeks in 58 unique patients*

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.

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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

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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.

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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.

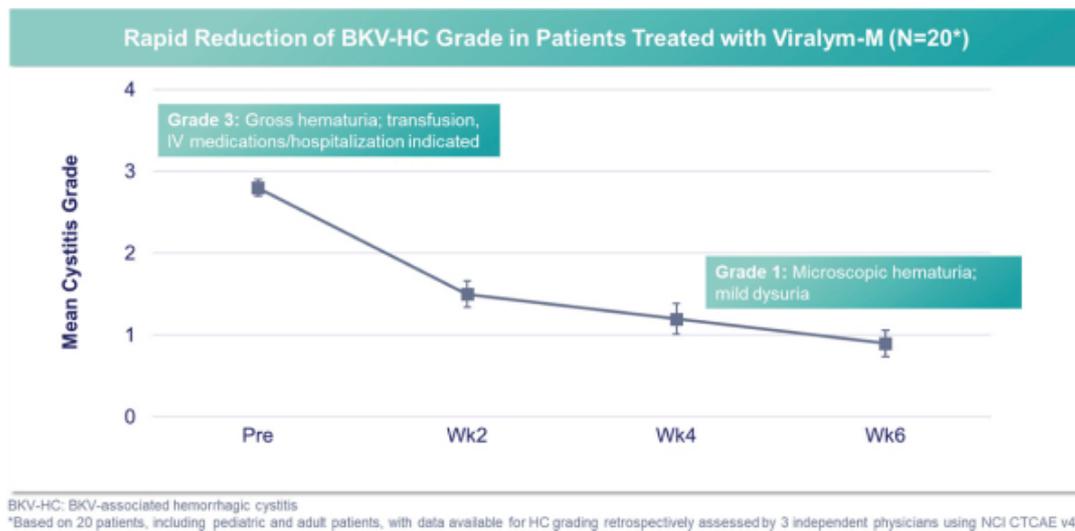


Figure 10. Rapid Grade Reduction of BKV HC following treatment with Viralym-M therapy.

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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.

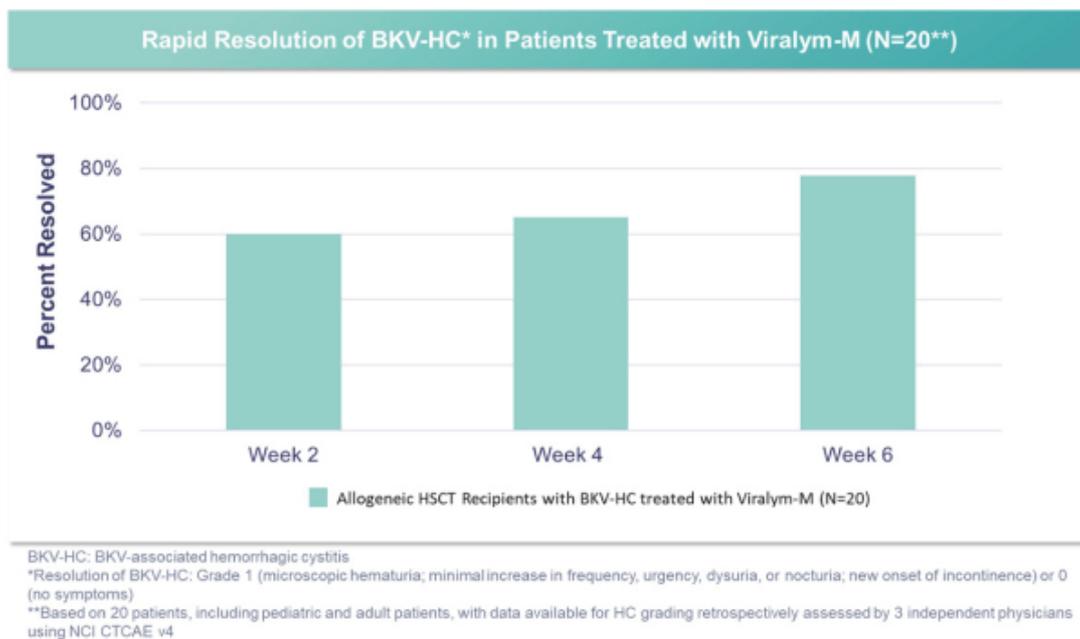


Figure 11. Time to resolution of BKV-HC following treatment with Viralym-M therapy

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 anticipate initiating our Phase 3 virus-associated-HC registrational trial in the fourth quarter of 2020. This Phase 3, multicenter, randomized, double-blind, placebo-controlled trial is designed to assess the safety and efficacy of Vivalym-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 Vivalym-M to reduce or eliminate viral loads for CMV, AdV, EBV, HHV-6 and JCV.

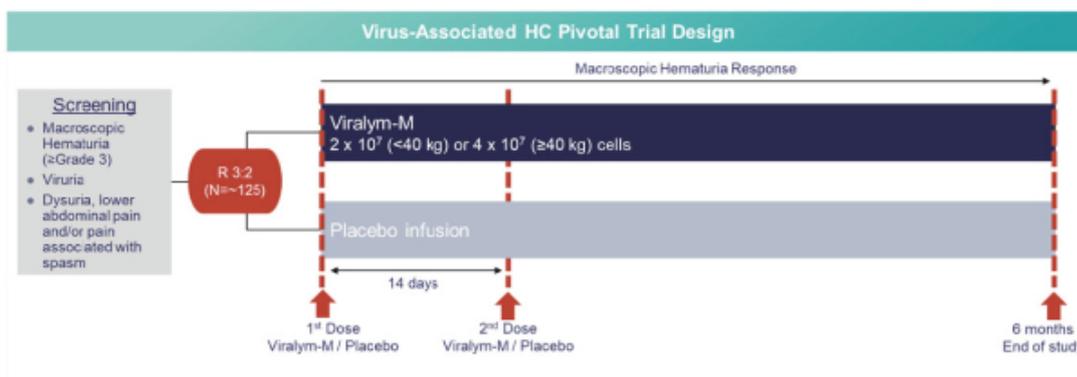


Figure 12. Phase 3, multicenter, randomized, double-blind, placebo-controlled virus-associated HC trial design

In addition to the PRIME and orphan drug designations granted by the EMA, Vivalym-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 plan to initiate our Phase 2, proof-of-concept trial with Vivalym-M for the prevention of clinically significant viral infection and disease in allogeneic HSCT patients in 2020, with initial data expected in 2021. We plan to evaluate Vivalym-M both as a prophylactic therapy in high-risk patients and as a preemptive therapy in patients who reactivate one or more of the targeted viruses. The trial is expected to be multicenter, randomized, double-blind, and placebo-controlled. This trial is designed to assess the safety and efficacy of Vivalym-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 plan to initiate a proof-of-concept trial with Vivalym-M for the treatment of BKV in KT patients in the first half of 2021, with interim data expected in 2021. This Phase 2 trial is expected to be multicenter, randomized, double-blind, placebo-controlled trial designed to assess the safety, tolerability and effectiveness of adoptively transferred Vivalym-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 Vivalym-M for the treatment of CMV infections in SOT patients in 2021.

Other Viruses Targeted by Vivalym-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 PTLN.

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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 PTLT, 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, PTLT 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

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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.

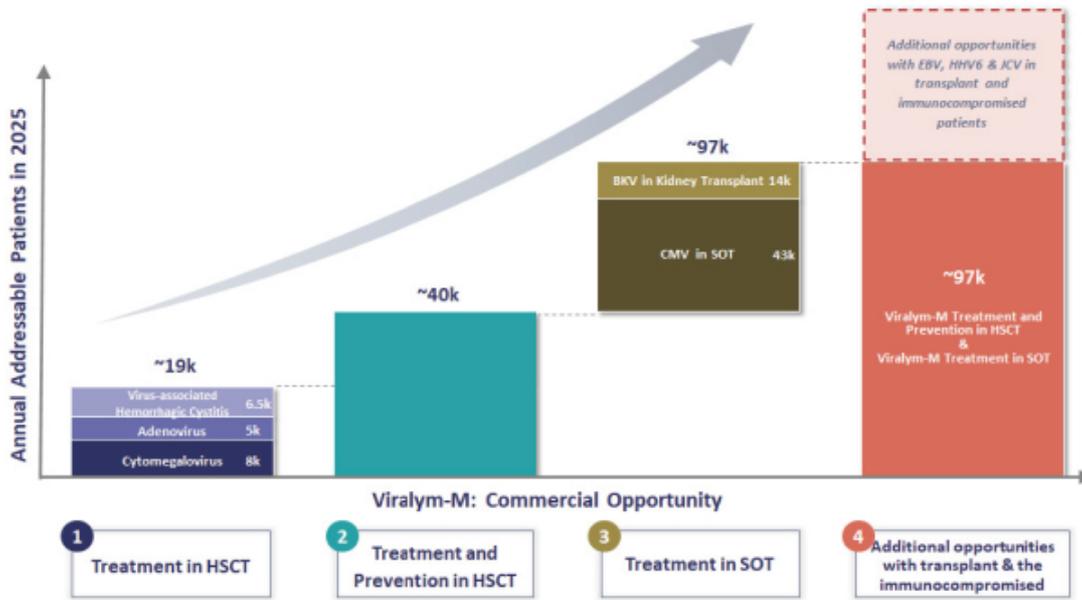


Figure 13. Viralym-M has a large market opportunity to treat and prevent devastating viral diseases

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.

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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.

	BKV-Hemorrhagic Cystitis	Adenovirus (AdV)	Cytomegalovirus (CMV)
Annual allogeneic HSCT population (2025)		~44,000	
Annual disease incidence	15%	32% in Peds 6% in adults	18%
Annual addressable patient population	6,500	5,000	8,000
Total annual addressable population in allogeneic HSCT		~19,500	

Table 3. Addressable population of potential patients for Vivalym-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, 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 Vivalym-M can accelerate the paradigm shift toward haploidentical HSCT and enable more patients to benefit from this curative HSCT procedure.

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

We are developing Vivalym-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 Vivalym-M. As 90% of allogeneic HSCT patients reactivate at least one virus targeted by Vivalym-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 Vivalym-M, if approved, has the potential to redefine the treatment landscape for viral diseases.

3—Vivalym-M Treatment for Solid Organ Transplant Patients

We are developing Vivalym-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 Vivalym-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 Vivalym-M therapy.

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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

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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 ($p<0.0001$).

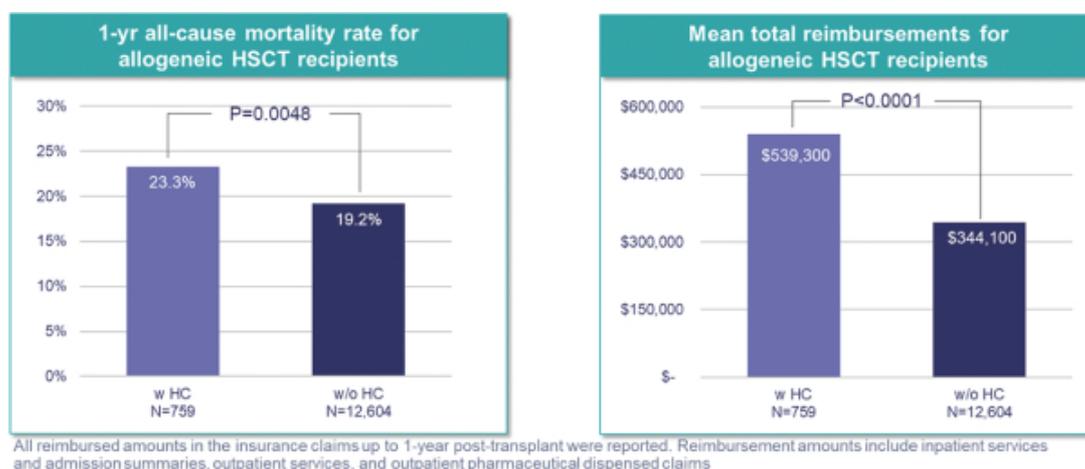


Figure 14. Real-world claims analysis confirms high clinical and economic burden of virus-associated HC.

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 July 2020, there were over 14 million confirmed SARS-CoV-2 cases and over 600,000 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.

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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 the fourth quarter of 2020 to target severe respiratory diseases in high-risk populations.

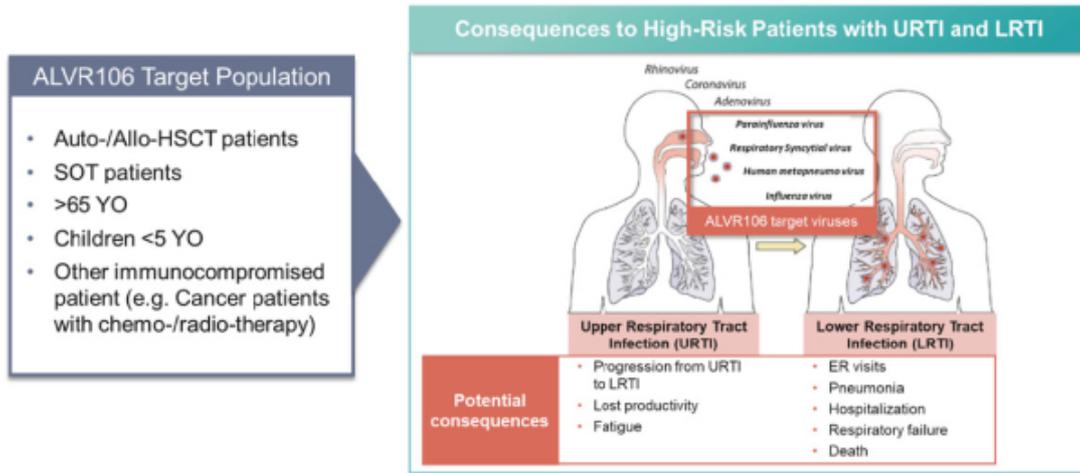


Figure 15: ALVR106 target populations and consequences to high-risk patients with respiratory virus infections

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.

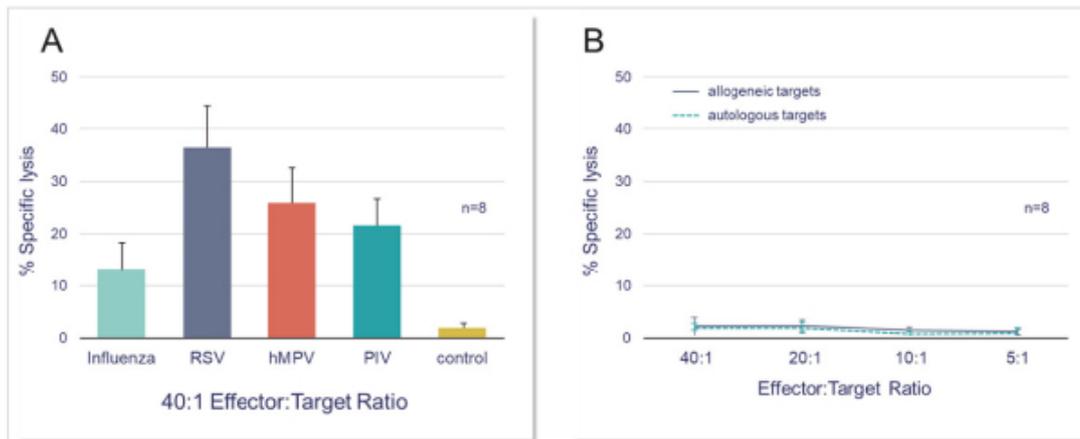


Figure 16. ALVR106 cells are reactive against virus-infected targets. (A) Cytolytic potential of ALVR106. Results are presented as percentage of specific lysis (mean±SEM). (B) Demonstration that multi-R-VST show minimal/no activity against either non-infected autologous or allogeneic PHA blasts.

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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 plan to submit an IND with the FDA for ALVR106 in the second half 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 fourth quarter of 2020, with initial

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data expected in 2021. 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.

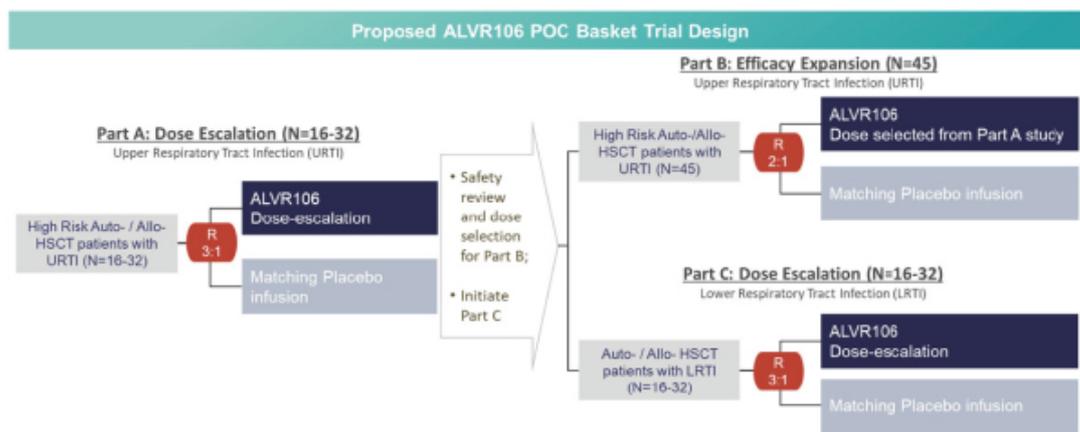


Figure 17. Proposed AVLRL06 Phase 1/2 Proof-of-concept basket trial design

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.

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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 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.

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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.

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

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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.

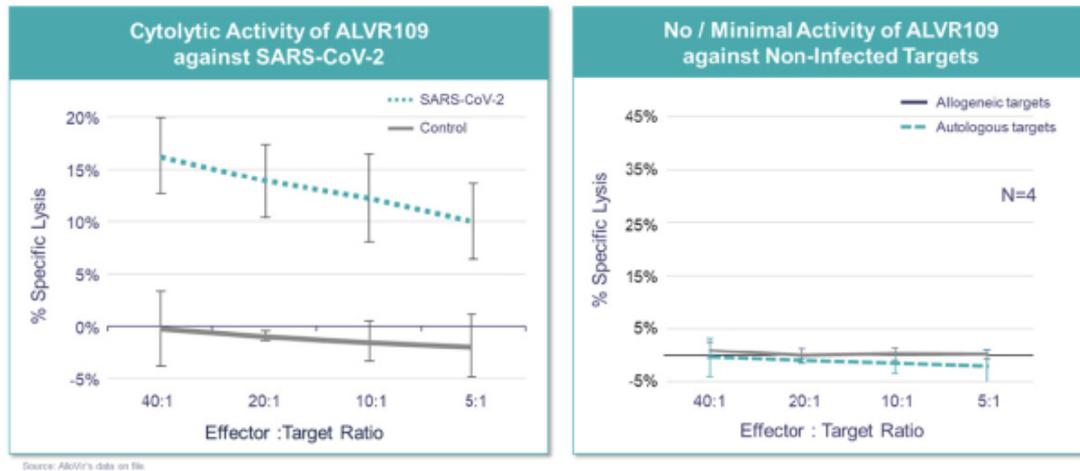


Figure 18. ALVR109 Has Demonstrated Selective Cytolytic Activity against SARS-CoV-2 While Leaving Non-Virus Infected Targets Intact

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, BCM plans to conduct a dose finding, proof-of-concept, single-center, randomized study to assess the safety and clinical effects of ALVR109 in high-risk COVID-19 patients. In its capacity as trial sponsor, BCM submitted an IND to the FDA in June 2020 for ALVR109 for the treatment of high-risk patients with COVID-19. Following IND submission, BCM reached alignment with the FDA on a revised clinical protocol. Subsequently, BCM was asked by the FDA to provide additional information regarding the quality specifications for ALVR109 specific ancillary reagents designed for use in the manufacturing process. These quality specifications were not immediately available at the time of the FDA's request in order to enable BCM to respond by the requested deadline. Consequently, the IND was placed on clinical hold for safety concerns related to the quality of ancillary reagents unique to ALVR109. Given that there is an urgent public health need to rapidly develop an effective therapy for COVID-19, we are collaborating with BCM to expeditiously provide the requested information to the FDA. While there can be no assurance regarding timing, we anticipate BCM will initiate a proof-of-concept trial in the second half of 2020, with top-line data expected in 2021.

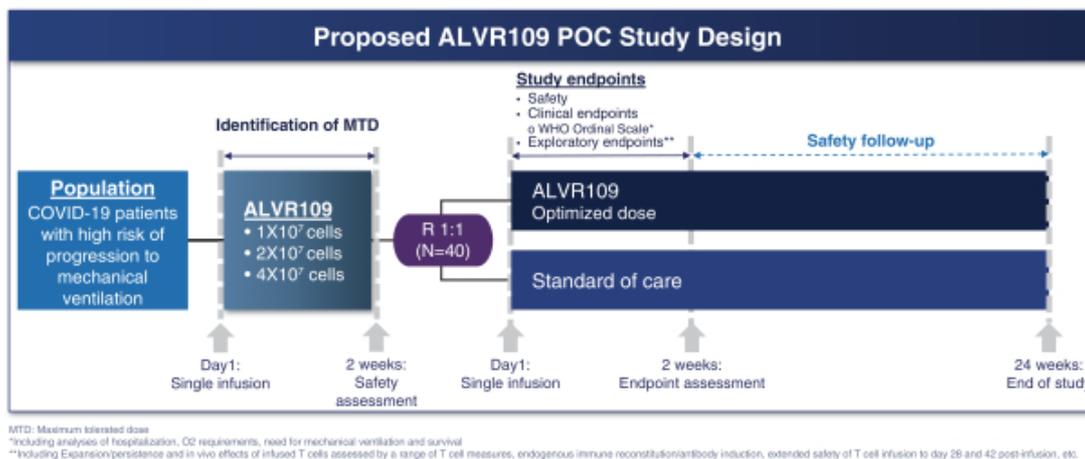


Figure 19. Proposed ALVR109 proof-of-concept trial design

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.

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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 submit an IND application with the FDA 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 large 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 submit an IND application with the FDA 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 tabellecleucel (tab-cel[®]), an off-the-shelf, allogeneic T cell immunotherapy, for HSCT and SOT patients with EBV+PTLD (EBV-associated post-transplant lymphoproliferative disease). We are not aware of any other cell therapies currently in clinical trials or preclinical development that target the same viruses as our VST product candidates.

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

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BKV-associated HC and AdV infections in HSCT patients. Additionally, Amplyx 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, is conducting 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: Remdesivir, developed by Gilead Sciences, Inc., and Hydroxychloroquine Sulfate have been granted Emergency Use Authorization by the FDA for the treatment of patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. There are several antiviral therapies and vaccines in clinical development, but there are currently no other FDA-approved antiviral therapies for the treatment or prevention of SARS-CoV-2 infections.

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 July 1, 2020, 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) and ALVR106, various pre-clinical product candidates, and our

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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 19 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 2040, 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 a provisional application 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 this patent application 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 two pending U.S. provisional applications 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 provisional applications 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

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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.

License Agreement

Amended and Restated Exclusive License Agreement with BCM

In May 2020, we entered into an amended and restated exclusive license agreement, or the BCM 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 BCM 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 BCM License Agreement in its entirety at any time for convenience upon a certain number of days' written notice. BCM may terminate the BCM 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 BCM 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 BCM 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 BCM 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

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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 BCM License Agreement, BCM would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits.

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;

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- 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

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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

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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.

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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

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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

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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

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

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

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

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products 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,

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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

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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.

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 health authority and an independent ethics committee, 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.

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.

Regulation in the European Union

In the European Union, medicinal products, including advanced therapy medicinal products, or ATMPs, are subject to extensive pre- and post-market regulation by regulatory authorities at both the European Union and national levels. ATMPs comprise gene therapy products, somatic cell therapy products and tissue engineered products, which are cells or tissues that have undergone substantial manipulation and that are administered to human beings in order to regenerate, repair or replace a human tissue. We anticipate that gene therapy development products would be regulated as ATMPs in the European Union under the Regulation on advanced therapy medicinal products, which is directly effective under the laws of all European Union Member States.

To obtain regulatory approval of an investigational product under European Union regulatory systems, we must submit a marketing authorization application, or MAA. 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, region-specific document requirements. An MAA holder for an ATMP in Europe must 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. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, innovative medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application during the eight year period. 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. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be an innovative medicinal product, and products may therefore not qualify for data exclusivity. Products with an orphan designation in the European Union 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 is intended for the diagnosis, prevention or treatment of (1) a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons in the European Union when the application is made; or (2) a life-threatening, seriously debilitating or serious and chronic condition in the European Union and that without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, 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.

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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 applicant consents to a second orphan medicinal product application; or
- The applicant cannot supply enough orphan medicinal product.

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

If we 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.

Pediatric Development

In the European Union, companies developing a new medicinal product must agree upon a Pediatric Investigation Plan, or PIP, with the EMA, 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 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, in which case the pediatric clinical trials must be completed at a later date. Products that are granted a marketing authorization on the basis of the 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) or, 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 PRIority Medicines (PRIME), scheme is intended to encourage drug development in areas of unmet medical need and provides accelerated assessment of products representing substantial innovation reviewed under the centralized procedure. 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.

Post-Approval Controls

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.

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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 remains applicable to the United Kingdom. This transition period is due to end 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. It remains to be seen how, if at all, Brexit will impact regulatory requirements for product candidates and products in the United Kingdom.

Coverage and Reimbursement

In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to 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 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

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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;

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- 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;
- 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 Affordable Care Act, or 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,

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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.

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 process personally identifiable information ("personal information"). In the United States, the Health Insurance Portability and Accountability Act of 1996, or 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 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

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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 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 will commence 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.

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. 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.

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

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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.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Various portions of the ACA are currently undergoing legal and constitutional challenges in the Fifth Circuit Court and the United States Supreme Court; the Trump Administration has issued various Executive Orders which eliminated cost sharing subsidies and various provisions 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; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the ACA. It is unclear whether the ACA will be overturned, repealed, replaced, or further amended. We cannot predict what affect further changes to the ACA would have on our business.

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 were suspended from May 1, 2020 through December 31, 2020 due to 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 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, starting in 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.

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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. The Trump administration 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. While a number of these and other proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

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 July 1, 2020, we had 21 full-time employees, including 6 with Ph.D. or M.D. degrees, and 10 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.

Facilities

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 on September 30, 2020. 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.

Legal Proceedings

As of the date of this prospectus, we are not party to any material legal matters or claims. We may become party to legal matters and claims arising in the ordinary course of business. We cannot predict the outcome of any such legal matters or claims, and despite the potential outcomes, the existence thereof may have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

The following table sets forth the name, age and position of each of our executive officers and directors, as of July 22, 2020. The following also includes certain information regarding our directors' and officers' individual experience, qualifications, attributes and skills and brief statements of those aspects of our directors' backgrounds that led us to conclude that they are qualified to serve as directors.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Executive Officers		
David Hallal	54	Chief Executive Officer and Director
Vikas Sinha	57	President, Chief Financial Officer and Director
Ann Leen	44	Chief Scientific Officer
Jeroen van Beek	57	Chief Commercial Officer
Agustin Melian	56	Chief Medical Officer
Brett Hagen	47	Chief Accounting Officer
Ercem Atillasoy	56	Chief Regulatory and Safety Officer
Edward Miller	56	General Counsel
Non-Employee Directors		
Jeffrey S. Bornstein ⁽¹⁾⁽²⁾	54	Director
Diana Brainard	49	Director
Malcolm Brenner, M.D. ⁽³⁾	68	Director
Ansbert Gadicke, M.D. ⁽¹⁾⁽³⁾	62	Director
Morana Jovan-Embiricos, Ph.D. ⁽¹⁾⁽²⁾	53	Director
Juan Vera	40	Director
John Wilson ⁽³⁾	61	Director

(1) Member of the Audit Committee

(2) Member of the Compensation Committee

(3) Member of the Nominating and Corporate Governance Committee

Executive Team

David Hallal has served as our Chairman and Chief Executive Officer since September 2018. Mr. Hallal has served as Chairman, Chief Executive Officer and Co-Founder of ElevateBio LLC, which he co-founded, since December 2017. Mr. Hallal serves as the Chairman of the board of directors of Scholar Rock Holding Corp. (Nasdaq: SRRK) and iTeos Therapeutics SA, and as a member of the board of directors of Seer Biosciences, Inc. Prior to that, from June 2006 to December 2016, Mr. Hallal served in executive roles of increasing responsibility at Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN), most recently serving as Chief Executive Officer and a board member. Prior to his role as CEO, Mr. Hallal served Alexion as COO and Director as well as Chief Commercial Officer and Head of Commercial Operations. Prior to Alexion, from 2004 to 2006, Mr. Hallal served as Vice President of Sales for OSI Eyetech, Inc. From 2002 to 2004, Mr. Hallal served as Head of Sales at Biogen Inc. (Nasdaq: BIIB). From 1992 to 2002, Mr. Hallal held various leadership roles at Amgen Inc (Nasdaq: AMGN). From 1988 to 1992, Mr. Hallal began his pharmaceutical career at The Upjohn Company as a sales representative. Mr. Hallal holds a B.A. in psychology from the University of New Hampshire. Our Board of Directors believes Mr. Hallal's experience as an executive at numerous pharmaceutical companies provides him with the qualifications and skills to serve as the Chairman of our Board of Directors.

Vikas Sinha has served as our President and Chief Financial Officer since January 2019. Mr. Sinha has over 20 years' experience working in executive finance roles in the life sciences industry. Mr. Sinha is Co-Founder and Chief Financial Officer of ElevateBio LLC. He also serves as a board member for ElevateBio LLC since February 2018. From 2005 to 2016, Mr. Sinha was the Chief Financial Officer of Alexion Pharmaceuticals, Inc. (Nasdaq: ALXN), a biotechnology company, where he was responsible for finance, business development, strategy, investor relations and IT. Prior to joining Alexion, Mr. Sinha held various positions with Bayer AG in the United States, Japan, Germany and Canada, including Vice President and Chief Financial Officer of Bayer Pharmaceuticals Corporation in the United States and Vice President and Chief Financial Officer of Bayer

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Yakuhin Ltd. in Japan. Mr. Sinha serves as a Non-Executive Director of the board of directors of Verona Pharma PLC (Nasdaq: VRNA). Mr. Sinha holds a master's degree in business administration from the Asian Institute of Management. He is also a qualified Chartered Accountant from the Institute of Chartered Accountants of India and a Certified Public Accountant in the United States. Our Board of Directors believes Mr. Sinha's experience as an executive in finance roles in the life sciences industry provides him with the qualifications and skills to serve on our Board of Directors.

Ann Leen, Ph.D., is a co-founder and has served as our consulting Chief Scientific Officer since 2013. Since 2019, she has been a Professor in the Department of Pediatrics at the Center for Cell and Gene Therapy, Baylor College of Medicine. From 2013 to 2019 she was an Associate Professor in the same department. Her work focuses on the development and clinical translation of novel T cell based therapies from the bench to the bedside. Dr. Leen is also a co-founder of Marker Therapeutics where she served as consulting Chief Scientific Officer from 2016 to February 2020. Dr. Leen received her B.S. in Biochemistry at the University of College Cork in Cork, Ireland and her Ph.D. in Immunology at the CRC Institute for Cancer Studies in Birmingham, UK.

Jeroen van Beek, Ph.D., has served as our Chief Commercial Officer since January 2019. Since October 2018, Dr. van Beek has served as a Sr. Commercial Advisor at ElevateBio LLC. Before joining AlloVir, Dr. van Beek was the Chief Commercial Officer and Senior Vice-President at Tricida in charge of commercial strategy, planning and operations from January 2018 to September 2018. From 2007 to 2017, Dr. van Beek worked at Alexion Pharmaceuticals, most recently as the Vice-President of Global Commercial Operations and Development in charge of the global Soliris® franchise. He was also responsible for the life-cycle management of Soliris® and the commercial development and positioning of Alexion's portfolio of next-generation complement inhibitors. During his tenure at Alexion, Dr. van Beek led the launches for Soliris® in two rare diseases: the blood disorder Paroxysmal Nocturnal Hemoglobinuria and the kidney disease atypical Hemolytic Uremic Syndrome. From 1999 to 2007, Dr. van Beek held positions of increasing commercial responsibility at Pfizer including Marketing Director, Oncology responsible for launching Sutent® for renal cell carcinoma and gastrointestinal stromal tumor. Dr. van Beek received his B.S. in Chemistry from the University of Virginia, his Ph.D. in Chemistry from Cornell University, and his M.B.A. from the Darden Business School at the University of Virginia.

Agustin Melian, M.D., has served as our Chief Medical Officer since April 2019. Before joining AlloVir, Dr. Melian served as VP and SVP in Global Clinical Development and Medical Sciences at Alexion Pharmaceuticals from 2013 to 2019. From 2000 to 2013, Dr. Melian held various different roles in clinical development at Merck. Prior to 2000 practiced Medicine and conducted Basic Immunology Research at The Brigham and Women's Hospital in Boston, Massachusetts. Dr. Melian also has a background in DNA transcription and repair. He received his B.S. degrees in Molecular Biophysics and Biochemistry and his M.D. in Medicine from Yale University.

Brett Hagen has served as our Chief Accounting Officer since January 2019. Prior to joining AlloVir, from February 2018 to August 2018, he served as Senior Director Finance and Accounting at Eloxx Pharmaceuticals. From May 2016 to December 2017, he served as Vice President, Finance and Controller at Proteostasis Therapeutics. From July 2014 to May 2016, he served as Controller at BIND Therapeutics. Mr. Hagen received his B.A. from the University of Minnesota, and graduate degrees in accounting and finance from Wright State University and Suffolk University, respectively.

Ercecm Atillasoy, M.D., has served as our Chief Regulatory and Safety Officer since July 2020. Before joining AlloVir, Dr. Atillasoy served in roles of increasing responsibility at Merck Research Laboratories since 2001, where he most recently served as the Vice President and Therapeutic Area head of Vaccines and Infectious Disease, in Global Regulatory Affairs and Clinical Safety. Dr. Atillasoy also served as Merck's senior representative to the PhRMA Regulatory Steering Group and the BIO's Vaccine Regulatory Advisory Committee. In 2019, he was selected as the Industry Representative to the FDA's Advisory Committee for the

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Division of Dermatologic and Ophthalmologic Products. Dr. Atillasoy received his B.A. in English from the City University of New York and his M.D. from the Yale University School of Medicine.

Edward Miller has served as our General Counsel since January 2019. Mr. Miller was a Consultant for the Company from October 2018 to December 2018. Since October 2018, he has served as a Consultant to ElevateBio Management, Inc. From May 2017 to September 2018, Mr. Miller was a Principal in Legal/Compliance consulting for Life Sciences Compliance Strategies. From July 2014 to April 2017, Mr. Miller was Senior Vice President and Chief Compliance Officer at Alexion Pharmaceuticals, Inc., as well as serving on Alexion's global executive management team. Prior to Alexion, Mr. Miller served in global and U.S.-based roles at Boehringer Ingelheim, including Vice President, Chief Compliance Officer and global Head of Litigation and Government Investigations. Mr. Miller received his J.D. from the Rutgers University School of Law and his Bachelor of Arts from Princeton University.

Non-Executive Directors

Jeffrey S. Bornstein has served as a member of our Board of Directors since July 2020. Mr. Bornstein serves as a managing partner of Whipstick Ventures and Generation Capital, and was the Chief Financial Officer and Vice Chairman of General Electric until October 2017. Previously, Mr. Bornstein served as a Senior Vice President and Chief Financial Officer of GE Capital. He is a trustee of Northeastern University, and a member of the Board of Directors of buildOn, Inc. Mr. Bornstein obtained his BS degree from Northeastern University. Our Board of Directors believes Mr. Bornstein's financial and senior management expertise provide him with the qualification and skills to serve on our Board of Directors.

Diana Brainard, M.D., has served as member of our Board of Directors since July 2020. Dr. Brainard has served as Senior Vice President and Virology Therapeutic Area Head at Gilead Sciences, Inc. since 2018, where she was previously Vice President of Liver Diseases from 2015 to 2018. Dr. Brainard obtained her BS degree from Brown University and her M.D. from Tulane University School of Medicine. Our Board of Directors believes Dr. Brainard's experience in the biotechnology industry provides her with the qualification and skills to serve on our Board of Directors.

Malcolm Brenner, M.B., B.Chir., M.D., Ph.D., is a co-founder of the Company and has served as a member of our Board of Directors since 2012. Since 1998, Dr. Brenner has worked at Baylor College of Medicine where he is currently the founding director of the Center for Cell and Gene Therapy and the Faye Sarofim Distinguished Service Professor at Baylor College of Medicine in the Departments of Medicine, Pediatrics, and Human and Molecular Genetics. He is also a member of the Texas Children's Cancer and Hematology Center, the Stem Cell and Regenerative Medicine Center, and the Dan L. Duncan Comprehensive Cancer Center at Baylor. Dr. Brenner has devoted his career as a physician-scientist to the field of stem cell transplantation through the therapeutic use of T cell immunologic approaches and genetic engineering strategies. He served as Editor-in-Chief of Molecular Therapy and as former President of the American Society for Gene and Cell Therapy (ASGCT) and International Society for Cell and Gene Therapy. He is an elected Member of the National Academy of Medicine. Dr. Brenner obtained his BA and medical degrees as well as his Ph.D. from the University of Cambridge in the UK where he became a fellow of the Royal College of Pathologists and the Royal College of Physicians. Our Board of Directors believes Dr. Brenner's expertise and experience in the genetic engineering of T cells for T cell therapy provide him with the qualification and skills to serve on our Board of Directors.

Ansbert Gadicke, M.D., has served as a member of our Board of Directors since September 2018. Dr. Gadicke co-founded MPM Capital's venture investing activities in 1997 and has since served as a Managing Director. Prior to that, Dr. Gadicke led MPM Capital's Advisory and Investment Banking business from 1992 to 1996 and was in Boston Consulting Group's Health Care Group from 1989 to 1992. Dr. Gadicke is a member of the board of directors of TCR² Therapeutics Inc. (Nasdaq: TCRR), Cullinan Oncology, LLC and ElevateBio, and formerly served as a member of the board of directors of Radius Health, Inc. (Nasdaq: RDUS) and Chiasma, Inc.

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(Nasdaq: CHMA). Dr. Gadicke received his M.D. from J.W. Goethe University and has held research positions at the Whitehead Institute and Harvard University. Our Board of Directors believes Dr. Gadicke is qualified to serve as a member of our Board of Directors because of his extensive experience in the life sciences industry and in investment management.

Morana Jovan-Embiricos, Ph.D., has served on our Board of Directors since May 2019. In 2003, Dr. Jovan co-founded F2 Ventures, a biotech venture capital platform and has since served as its Managing Partner. Prior to joining F2 Ventures, Dr. Jovan was a partner at MPM Capital. Dr. Jovan currently serves on the boards of directors of Damon Runyon Cancer Center Research Foundation, TriNetX, Inc. and Cullinan Oncology. Dr. Jovan received her Ph.D. in biophysical chemistry from the University of Cambridge and was a post-doctoral fellow at Harvard University. Our Board of Directors believes Dr. Jovan is qualified to serve as a member of our Board of Directors because of her scientific background and experience in the venture capital industry.

John Wilson is a co-founder of the Company and has served as a member of our Board of Directors since 2018. From 2013 to 2018 he was the Managing Member of the Company. Mr. Wilson brings extensive experience in commercial scale production of T cells for T cell therapy. Mr. Wilson served as Chief Executive Officer of Marker Therapeutics, Inc., which he co-founded, from 2015 to 2018, and currently serves as a member of the board of directors (Nasdaq: MRKR). Since 1996, he has been CEO of Wilson Wolf Manufacturing Corporation, which designs, develops and manufactures cell culture devices for the field of biotechnology. He has obtained over 50 related patents with numerous patents currently pending. Mr. Wilson is a co-inventor of the G-Rex cell culture platform, which is widely used for large-scale production of T cells, and is a co-inventor of Marker Therapeutics' multi-tumor associated antigen technology. Mr. Wilson has a B.A. in Business Administration and a B.A. in Economics from Hamline University in Minnesota, and a B.S. in Mechanical Engineering from the University of Minnesota. Our Board of Directors believes Mr. Wilson's expertise and experience in the production of T cells for T cell therapy provide him with the qualification and skills to serve on our Board of Directors.

Juan Vera, M.D., is our co-founder and has served as Chief Product Development Officer from January 2014 to June 2020. Dr. Vera has served as the Chief Development Officer and a member of the Board of Directors of Marker Therapeutics (Nasdaq: MRKR) since October 2018. Dr. Vera was trained as a medical surgeon, and since 2004 has held different positions at the Center for Cell and Gene Therapy, or CAGT, at Baylor College of Medicine, first as a postdoctoral associate from 2004 to 2008, an instructor from 2009 to 2010, an Assistant Professor from 2011 to 2014 and an Associate Professor from 2015 to the present. Dr. Vera received his M.D. from the University El Bosque in Bogota, Colombia. Our Board of Directors believes Dr. Vera's experience performing research in the field of adoptive T cell therapy provides him with the qualification and skills to serve on our Board of Directors.

Composition of Our Board of Directors

Our board of directors consists of nine members, each of whom are members pursuant to the board composition provisions of our amended and restated certificate of incorporation and agreements with our stockholders. These board composition provisions will terminate upon the completion of this offering. Upon the termination of these provisions, there will be no further contractual obligations regarding the election of our directors. Our nominating and corporate governance committee and our board of directors may therefore consider a broad range of factors relating to the qualifications and background of nominees. Our nominating and corporate governance committee's and our board of directors' priority in selecting board members is the identification of persons who will further the interests of our stockholders through their established record of professional accomplishment, the ability to contribute positively to the collaborative culture among board members, knowledge of our business, understanding of the competitive landscape, and professional and personal experiences and expertise relevant to our growth strategy. Our directors hold office until their successors have been elected and qualified or until the earlier of their resignation or removal. Our amended and restated certificate of incorporation that will become effective upon the closing of this offering and our amended and

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restated bylaws that became effective on the date on which the registration statement of which this prospectus is a part is declared effective by the SEC also provide that our directors may be removed only for cause by the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Director Independence

Our board of directors has determined that all members of the board of directors, except David Hallal, Vikas Sinha and Juan Vera, are independent directors, including for purposes of the rules of The Nasdaq Global Select Market and the Securities and Exchange Commission, or SEC. In making such independence determination, our board of directors considered the relationships that each non-employee director has with us and all other facts and circumstances that our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. In considering the independence of the directors listed above, our board of directors considered the association of our directors with the holders of more than 5% of our common stock. Upon the completion of this offering, we expect that the composition and functioning of our board of directors and each of our committees will comply with all applicable requirements of The Nasdaq Global Select Market and the rules and regulations of the SEC. There are no family relationships among any of our directors or executive officers. are not independent directors under these rules because they are current or former employees of our company.

Classified Board

In accordance with the terms of our amended and restated certificate of incorporation that will become effective upon the closing of this offering and our amended and restated bylaws that became effective on the date on which the registration statement of which this prospectus is a part is declared effective by the SEC, our board of directors will be divided into three staggered classes of directors and each will be assigned to one of the three classes. At each annual meeting of the stockholders, a class of directors will be elected for a three-year term to succeed the directors of the same class whose terms are then expiring. The terms of the directors will expire upon the election and qualification of successor directors at the annual meeting of stockholders to be held during the years 2021 for Class I directors, 2022 for Class II directors and 2023 for Class III directors.

- Our Class I directors will be Juan Vera, Ansbert Gadick and Morana Jovan-Embircos;
- Our Class II directors will be Vikas Sinha, Malcolm Brenner and John Wilson; and
- Our Class III directors will be Jeffrey Bornstein, Diana Brainard and David Hallal.

Our amended and restated certificate of incorporation that will become effective upon the closing of this offering and our amended and restated bylaws that will become effective on the date the registration statement of which this prospectus is a part is declared effective by the SEC will provide that the number of directors shall be fixed from time to time by a resolution of the majority of our board of directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent stockholder efforts to effect a change of our management or a change in control.

Board Leadership Structure and Board's Role in Risk Oversight

We face a number of risks, including risks relating to our financial condition, development and commercialization activities, operations, strategic direction and intellectual property as more fully discussed in the section entitled "Risk Factors" appearing elsewhere in this prospectus. Management is responsible for the day-to-day management of risks we face, while our board of directors, as a whole and through its committees, has responsibility for the oversight of risk management. In its risk oversight role, our board of directors has the responsibility to satisfy itself that the risk management processes designed and implemented by management are adequate and functioning as designed.

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The role of the board of directors in overseeing the management of our risks is conducted primarily through committees of the board of directors, as disclosed in the descriptions of each of the committees below and in the charters of each of the committees. The full board of directors (or the appropriate board committee in the case of risks that are under the purview of a particular committee) discusses with management our major risk exposures, their potential impact on us, and the steps we take to manage them. When a board committee is responsible for evaluating and overseeing the management of a particular risk or risks, the chairman of the relevant committee reports on the discussion to the full board of directors during the committee reports portion of the next board meeting. This enables the board of directors and its committees to coordinate the risk oversight role, particularly with respect to risk interrelationships.

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee, each of which will operate pursuant to a charter adopted by our board of directors and will be effective upon the effectiveness of the registration statement of which this prospectus is a part. Upon the effectiveness of the registration statement of which this prospectus is a part, the composition and functioning of all of our committees will comply with all applicable requirements of the Sarbanes-Oxley Act of 2002, Nasdaq and SEC rules and regulations.

Audit Committee

Jeffrey Bornstein, Morana Jovan-Embiricos and Ansbert Gadicke will serve on the audit committee, which will be chaired by Jeffrey Bornstein. Our board of directors has determined that each member of the audit committee is “independent” for audit committee purposes as that term is defined in the rules of the SEC and the applicable Nasdaq rules, and each has sufficient knowledge in financial and auditing matters to serve on the audit committee. Our board of directors has designated Jeffrey Bornstein as an “audit committee financial expert,” as defined under the applicable rules of the SEC. The audit committee’s responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our independent registered public accounting firm;
- pre-approving auditing and permissible non-audit services, and the terms of such services, to be provided by our independent registered public accounting firm;
- reviewing the overall audit plan with our independent registered public accounting firm and members of management responsible for preparing our consolidated financial statements;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures as well as critical accounting policies and practices used by us;
- coordinating the oversight and reviewing the adequacy of our internal control over financial reporting;
- establishing policies and procedures for the receipt and retention of accounting-related complaints and concerns;
- recommending, based upon the audit committee’s review and discussions with management and our independent registered public accounting firm, whether our audited consolidated financial statements shall be included in our Annual Report on Form 10-K;
- monitoring the integrity of our consolidated financial statements and our compliance with legal and regulatory requirements as they relate to our consolidated financial statements and accounting matters;
- preparing the audit committee report required by SEC rules to be included in our annual proxy statement;

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- reviewing all related person transactions for potential conflict of interest situations and voting with respect to all such transactions; and
- reviewing quarterly earnings releases.

Compensation Committee

Morana Jovan-Embiricos and Jeffrey Bornstein will serve on the compensation committee, which will be chaired by Morana Jovan-Embiricos. Our board of directors has determined that each member of the compensation committee is “independent” as defined in the applicable Nasdaq rules. The compensation committee’s responsibilities include:

- annually reviewing and recommending to the board of directors the corporate goals and objectives relevant to the compensation of our principal executive officer;
- evaluating the performance of our principal executive officer in light of such corporate goals and objectives and based on such evaluation recommending to the board for determination the equity and non-equity compensation of our principal executive officer;
- determining and approving the equity and non-equity compensation of our other executive officers;
- reviewing and establishing our overall management compensation, philosophy and policy;
- overseeing and administering our compensation and similar plans;
- evaluating and assessing potential and current compensation advisors in accordance with the independence standards identified in the applicable Nasdaq rules;
- reviewing and approving our policies and procedures for the grant of equity-based awards;
- reviewing and recommending to the board of directors the compensation of our directors;
- preparing the compensation committee report required by SEC rules, if and when required, to be included in our annual proxy statement; and
- reviewing and approving the retention, termination or compensation of any consulting firm or outside advisor to assist in the evaluation of compensation matters.

Nominating and Corporate Governance Committee

Malcolm Brenner, Ansbert Gadicke and John Wilson will serve on the nominating and corporate governance committee, which will be chaired by Malcolm Brenner. Our board of directors has determined that each member of the nominating and corporate governance committee is “independent” as defined in the applicable Nasdaq rules. The nominating and corporate governance committee’s responsibilities include:

- developing and recommending to the board of directors criteria for board and committee membership;
- establishing procedures for identifying and evaluating board of director candidates, including nominees recommended by stockholders;
- reviewing the composition of the board of directors to ensure that it is composed of members containing the appropriate skills and expertise to advise us;
- identifying individuals qualified to become members of the board of directors;
- recommending to the board of directors the persons to be nominated for election as directors and to each of the board’s committees;
- developing and recommending to the board of directors a code of business conduct and ethics and a set of corporate governance guidelines; and
- overseeing the evaluation of our board of directors and management.

Our board of directors may from time to time establish other committees.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has at any time during the prior three years been one of our officers or employees. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or compensation committee.

Corporate Governance

We have adopted a written code of business conduct and ethics, effective upon the effectiveness of the registration statement of which this prospectus is a part, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. Following the effectiveness of the registration statement of which this prospectus is a part, a current copy of the code will be posted on the investor relations section of our website, which is located at www.AlloVir.com. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website or in a current report on Form 8-K.

EXECUTIVE COMPENSATION**Executive Compensation Overview**

The following discussion contains forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. The actual amount and form of compensation and the compensation policies and practices that we adopt in the future may differ materially from currently planned programs as summarized in this discussion.

The compensation provided to our named executive officers for the fiscal year ended December 31, 2019 is detailed in the Summary Compensation Table and accompanying footnotes and narrative that follow this section.

Our named executive officers for the fiscal year ended December 31, 2019, which consists of our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer, are:

- David Hallal, our Chief Executive Officer;
- Vikas Sinha, our President and Chief Financial Officer; and
- Agustin Melian, Chief Medical Officer.

2019 Summary Compensation Table

The following table presents information regarding the total compensation awarded to, earned by, and paid to our named executive officers for services rendered to us in all capacities for the fiscal year ended December 31, 2019.

<u>Name and principal position</u>	<u>Year</u>	<u>Salary (\$)</u>	<u>Bonus (\$)(1)</u>	<u>Stock awards(2) (\$)</u>	<u>Option awards (\$)</u>	<u>Non-equity incentive plan compensation (\$)(3)</u>	<u>All other compensation (\$)</u>	<u>Total (\$)</u>
David Hallal <i>Chief Executive Officer</i>	2019	550,000	5,000	2,677,235	—	330,000	2,875(4)	3,565,110
Vikas Sinha <i>President and Chief Financial Officer</i>	2019	400,000	5,000	1,029,746	—	192,000	2,900(5)	1,629,646
Agustin Melian(6) <i>Chief Medical Officer</i>	2019	326,276	—	1,599,523	—	143,157	20,006(7)	2,088,962

- (1) The amount reported represents one-time bonuses paid in connection with entering into updated employment agreements with the Company, providing for, among other things, the executives agreeing to certain restrictive covenants.
- (2) The amount reported represents the aggregate grant date fair value of the shares of restricted stock awarded to the named executive officers during the 2019 fiscal year, calculated in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the restricted stock reported in this column are set forth in Note 2 to our audited consolidated financial statements and Note 11 to our unaudited interim consolidated financial statements included elsewhere in this prospectus. The amount reported in this column reflects the accounting cost for these restricted stock awards and does not correspond to the actual economic value that may be received by the named executive officers upon the vesting of the shares of restricted stock or any sale of the shares.
- (3) Amounts reported represent bonuses paid upon achievement upon corporate performance goals for 2019.
- (4) The amount reported represents \$2,875 for matching contributions made by the Company under its 401(k) plan.
- (5) The amount reported represents \$2,900 for matching contributions made by the Company under its 401(k) plan.
- (6) Mr. Melian commenced employment with the Company on March 21, 2019.
- (7) The amount reported represents \$15,384 for commuting reimbursements and \$4,622 for tax-gross ups paid by the Company for commuting reimbursements.

Narrative to Summary Compensation Table

Base Salaries

We use base salaries to recognize the experience, skills, knowledge and responsibilities required of all our employees, including our named executive officers. Base salaries are reviewed annually, typically in connection with our annual performance review process, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience. Our named executive officers' 2019 annual base salaries are described below under "—Employment Arrangements with Our Named Executive Officers".

Bonuses

Our named executive officers are eligible to receive annual performance bonuses based on the achievement of certain corporate performance goals, which may be further modified by assessment of individual performance. We believe such bonuses properly incentivize our named executive officers and allow us to remain competitive within the marketplace. During 2019, each of Messrs. Hallal, Sinha and Melian were entitled to receive a target bonus of up to 50%, 40% and 35% of his base salary, respectively. Following the end of 2019, our compensation committee determined that we had achieved 120% of our corporate goals for fiscal year 2019 and determined to pay the bonuses as set forth in the "Non-Equity Incentive Compensation" column in the "Summary Compensation" table above.

Equity Compensation

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, we believe that equity grants provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. During the year ended December 31, 2019, we granted awards of restricted stock pursuant to our 2018 Plan (described in further detail below) to each of the named executive officers, as described in more detail in the "Outstanding Equity Awards at 2019 Fiscal Year-End" table.

Employment Arrangements with Our Named Executive Officers

David Hallal

On October 2, 2019, the Company and David Hallal entered into an Amended and Restated Employment Agreement, or the 2019 Hallal Employment Agreement, which provides for an initial annual base salary of \$550,000 and an annual target bonus opportunity of 50% of Mr. Hallal's then current base salary. The 2019 Hallal Employment Agreement additionally provides that, notwithstanding the terms of any equity agreements or plans pursuant to which Mr. Hallal is granted equity in the Company, all of his unvested equity shall vest upon the close of a Sale Event (as defined in the 2018 Plan). In connection with the 2019 Hallal Employment Agreement, the Company and Mr. Hallal also entered into a Restrictive Covenants Agreement (attached as Exhibit A to the 2019 Hallal Employment Agreement), and in consideration for which Mr. Hallal received a one-time cash payment of \$5,000.

Pursuant to the 2019 Hallal Employment Agreement, if Mr. Hallal's employment (i) is terminated without Cause (as defined in the 2019 Hallal Employment Agreement) or (ii) if he terminates his employment for Good Reason (as defined in the 2019 Hallal Employment Agreement), then Mr. Hallal shall be entitled to (i) a lump sum payment equal to (a) 24 months, so long as the Company is a privately-owned company or (b) 36 months, if the Company becomes a publicly-traded company on the Nasdaq or NYSE, or the Hallal Severance Period, of his then current base salary, (ii) a lump sum payment equal to his target annual bonus (together with the lump sum payment described in (i) above, the Hallal Severance Amount), provided that notwithstanding the foregoing, in

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the event Mr. Hallal is entitled to any payments pursuant to the Restrictive Covenants Agreement, the Hallal Severance Amount shall be reduced by the amount Mr. Hallal is paid pursuant to the Restrictive Covenants Agreement, (iii) provided Mr. Hallal timely elects to continue health coverage under the Consolidated Omnibus Budget Reconciliation Act of 1986, or COBRA, reimbursement for any monthly COBRA premium payments made by Mr. Hallal, until the earlier of (a) the expiration of the Hallal Severance Period, (b) Mr. Hallal's eligibility for group medical plan benefits under any other employer's group medical plan, or (c) the cessation of Mr. Hallal's continuation rights under COBRA, and (iv) the immediate vesting of any non-vested equity-related instruments.

Payment of the foregoing severance amounts is contingent upon Mr. Hallal's executing a separation and release agreement in a form and manner satisfactory to the Company, which shall include, without limitation, (i) a general release of claims against the Company and all related persons and entities, a reaffirmation of all of Mr. Hallal's Continuing Obligations (as defined in the 2019 Hallal Employment Agreement), and, in the Company's sole discretion, a one-year post-employment non-competition restriction in a form substantially similar to the Non-Competition Restriction (as defined in the Restrictive Covenants Agreement) and (ii) such separation and release becoming irrevocable within 60 days following Mr. Hallal's termination.

Pursuant to the 2019 Hallal Employment Agreement, in the event of Mr. Hallal's death or Disability (as defined in the 2019 Hallal Employment Agreement), any unvested stock options held by him will be accelerated in an amount equal to 25% plus 5% for each year of service to the Company of the number of shares subject to the option.

Pursuant to the 2019 Hallal Employment Agreement, if any payments or benefits provided to Mr. Hallal constitute "parachute payments" within the meaning of Section 280G of the Code, and any such payments are subject to the excise tax imposed by Section 4999 of the Code, Mr. Hallal's payments shall be payable either (i) in full or (ii) reduced to such lesser amount that results in no portion of such payments being subject to the excise tax, whichever results in the greater after-tax benefit to Mr. Hallal.

Vikas Sinha

On October 2, 2019, the Company and Vikas Sinha entered into an Amended and Restated Employment Agreement, or the 2019 Sinha Employment Agreement, which provides for an annual base salary of \$400,000 and an annual target bonus opportunity of 40% of Mr. Sinha's then current base salary. The 2019 Sinha Employment Agreement additionally provides that, notwithstanding the terms of any equity agreements or plans pursuant to which Mr. Sinha is granted equity in the Company, all unvested equity shall vest upon the close of a Sale Event (as defined in the 2018 Plan). In connection with the 2019 Sinha Employment agreement, the Company and Mr. Sinha also entered into a Restrictive Covenants Agreement (attached as Exhibit A to the 2019 Sinha Employment Agreement), and in consideration for which Mr. Sinha received a one-time cash payment of \$5,000.

Pursuant to the 2019 Sinha Employment Agreement, if Mr. Sinha's employment (i) is terminated without Cause (as defined in the 2019 Sinha Employment Agreement) or (ii) if he terminates his employment for Good Reason (as defined in the 2019 Sinha Employment Agreement), then Mr. Sinha shall be entitled to (i) a lump sum payment equal to (a) 18 months, so long as the Company is a privately-owned company or (b) 24 months, if the Company becomes a publicly-traded company on the Nasdaq or NYSE, or the Sinha Severance Period, of his then current base salary, (ii) a lump sum payment equal to his target annual bonus (together with the lump sum payment described in (i) above, the Sinha Severance Amount), provided that notwithstanding the foregoing, in the event Mr. Sinha is entitled to any payments pursuant to the Restrictive Covenants Agreement, the Sinha Severance Amount shall be reduced by the amount Mr. Sinha is paid pursuant to the Restrictive Covenants Agreement, (iii) provided Mr. Sinha timely elects to continue health coverage under COBRA, reimbursement for any monthly COBRA premium payments made by Mr. Sinha, until the earlier of (a) the expiration of the Sinha Severance Period, (b) Mr. Sinha's eligibility for group medical plan benefits under any other employer's group

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medical plan, or (c) the cessation of Mr. Sinha's continuation rights under COBRA, and (iv) the immediate vesting of any non-vested equity-related instruments.

Payment by the Company of the foregoing severance amounts is contingent upon Mr. Sinha's executing a separation and release agreement in a form and manner satisfactory to the Company, which shall include, without limitation, (i) a general release of claims against the Company and all related persons and entities, a reaffirmation of all of Mr. Sinha's Continuing Obligations (as defined in the 2019 Sinha Employment Agreement), and, in the Company's sole discretion, a one-year post-employment non-competition restriction in a form substantially similar to the Non-Competition Restriction (as defined in the Restrictive Covenants Agreement) and (ii) such separation and release becoming irrevocable within 60 days following Mr. Sinha's termination.

Pursuant to the 2019 Sinha Employment Agreement, in the event of Mr. Sinha's death or Disability (as defined in the 2019 Sinha Employment Agreement), any unvested stock options held by him will be accelerated in an amount equal to 25% plus 5% for each year of service to the Company of the number of shares subject to the option.

Pursuant to the 2019 Sinha Employment Agreement, if any payments or benefits provided to Mr. Sinha constitute "parachute payments" within the meaning of Section 280G of the Code, and any such payments are subject to the excise tax imposed by Section 4999 of the Code, Mr. Sinha's payments shall be payable either (i) in full or (ii) reduced to such lesser amount that results in no portion of such payments being subject to the excise tax, whichever results in the greater after-tax benefit to Mr. Sinha.

Agustin Melian

On March 21, 2019, the Company and Agustin Melian entered into an Employment Agreement, or the 2019 Melian Employment Agreement, which provides for an initial annual base salary of \$435,000 and an annual target bonus opportunity of 35% of Mr. Melian's then current base salary. Mr. Melian is also party to a consulting agreement with ElevateBio Management, Inc. Should ElevateBio Management terminate the consulting agreement for any reason other than for cause, the Company agrees to increase Mr. Melian's base salary in an amount equal to the annual consulting payment, not to exceed 25% of Mr. Melian's then current base salary. In addition, Mr. Melian was eligible for an initial award of 531,365 shares of restricted stock in the Company under the 2018 Plan, which vests as indicated below in the Outstanding Equity Awards at 2019 Fiscal Year End table, and is further eligible for an annual equity award, subject to approval of the Board. All unvested equity shall immediately vest upon a Sale Event (as described in the 2018 Plan).

Pursuant to the 2019 Melian Employment Agreement, if Mr. Melian's employment (i) is terminated without Cause (as defined in the 2019 Melian Employment Agreement) or (ii) if he terminates his employment for Good Reason (as defined in the 2019 Melian Employment Agreement), then Mr. Melian shall be entitled to (i) a lump sum payment equal to 12 months, or the Severance Period, of his then current base salary, (ii) a lump sum payment equal to his target annual bonus, (iii) provided Mr. Melian timely elects to continue health coverage under COBRA reimbursement for any monthly COBRA premium payments made by Mr. Melian during the Severance Period and (iv) the immediate vesting of any non-vested equity-related instruments.

Payment by the Company of the foregoing severance amounts is contingent upon (i) Mr. Melian's executing a general release agreement in favor of the Company, which shall contain reasonable and customary provisions, but shall not contain any post-employment restrictive covenants, and (ii) such release becoming effective within 60 days following Mr. Melian's termination.

Pursuant to the 2019 Melian Employment Agreement, in the event of Mr. Melian's death or Disability (as defined in the 2019 Melian Employment Agreement), any unvested stock options held by him will be accelerated in an amount equal to 25% plus 5% for each year of service to the Company of the number of shares subject to the option.

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Pursuant to the 2019 Melian Employment Agreement, if any payments or benefits provided to Mr. Melian constitute “parachute payments” within the meaning of Section 280G of the Code, and any such payments are subject to the excise tax imposed by Section 4999 of the Code, Mr. Melian’s payments shall be payable either (i) in full or (ii) reduced to such lesser amount that results in no portion of such payments being subject to the excise tax, whichever results in the greater after-tax benefit to Mr. Melian.

Outstanding Equity Awards at 2019 Fiscal Year-End

The following table sets forth information concerning outstanding equity awards held by each of our named executive officers as of December 31, 2019. All equity awards set forth in the table below were granted under our 2018 Plan.

<u>Name</u>	<u>Stock Awards(1)</u>	
	<u>Number of Shares or Units of Stock That Have Not Vested (#)</u>	<u>Market Value of Shares or Units of Stock That Have Not Vested \$(5)</u>
David Hallal	1,214,250(2)	\$ 20,642,250
	583,653(3)	\$ 9,922,101
Vikas Sinha	467,016(2)	\$ 7,939,272
	224,476(3)	\$ 3,816,092
Agustin Melian	531,360(4)	\$ 9,033,120

(1) Represents awards of restricted stock granted to our named executive officers under our 2018 Plan.

(2) 25% of the shares subject to this restricted stock award vested on December 3, 2018, with the remainder vesting in 16 equal quarterly installments thereafter, subject to continued service. Upon a sale event, a termination by the company without “cause” or a resignation for “good reason,” such restricted stock award shall accelerate and vest in full. In addition, in the event of termination due to death or disability, the next tranche of shares scheduled to vest will vest.

(3) 25% of the shares subject to this restricted stock award vested on June 10, 2019, with the remainder vesting in 16 equal quarterly installments thereafter, subject to continued service. Upon a sale event, such restricted stock award shall accelerate and vest in full.

(4) 25% of the shares subject to this restricted stock award vested on March 21, 2020, with the remainder vesting in 12 equal quarterly installments thereafter, subject to continued service. Upon a sale event, such restricted stock award shall accelerate and vest in full.

(5) The market price of our common stock is based on the initial public offering price of the common stock of \$17.00 per share.

Equity Grants to Named Executive Officers in Connection with our Initial Public Offering

In July 2020, our board of directors approved option grants to our named executive officers that will be effective upon our initial public offering. The options will be granted contingent and effective upon the effectiveness of the registration statement of which this prospectus forms a part. The options will be granted under our 2020 Plan and have an exercise price per share equal to the initial public offering price in this offering. The options will vest and become exercisable as follows: 25% of the shares subject to each stock option shall vest on the first anniversary of the effective date of the grant and the remaining 75% of the shares subject to each stock option shall vest in 12 equal quarterly installments thereafter, subject to the named executive officer’s continued service to us through each applicable vesting date. We granted options to purchase an aggregate of 1,758,000 shares of our common stock to our named executive officers upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share.

Employee Benefit and Equity Compensation Plans

2020 Stock Option and Grant Plan

Our 2020 Stock Option and Grant Plan, or 2020 Plan, was adopted by our board of directors on July 2, 2020, and approved by our stockholders in July 2020 and became effective as of the date immediately prior to the

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date of the effectiveness of the registration statement of which this prospectus is a part. The 2020 Plan allows the board of directors' compensation committee to make equity-based incentive awards to our officers, employees, directors and other key persons (including consultants). The 2020 Plan replaced our 2018 Plan. Our 2020 Plan provides flexibility to our compensation committee to use various equity-based incentive awards as compensation tools to motivate our workforce.

We have initially reserved 8,008,734 shares of our common stock, or the Initial Limit, for the issuance of awards under the 2020 Plan. The 2020 Plan provides that the number of shares reserved and available for issuance under the plan will automatically increase each January 1, beginning on January 1, 2021, by 5% of the outstanding number of shares of our common stock on the immediately preceding December 31 or such lesser number of shares as determined by our compensation committee, or the Annual Increase. This number is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

The shares we issue under the 2020 Plan will be authorized but unissued shares or shares that we reacquire. The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without any issuance of stock, expire or are otherwise terminated (other than by exercise) under each of the 2020 Plan and the 2018 Plan will be added back to the shares of common stock available for issuance under the 2020 Plan.

The maximum aggregate number of shares that may be issued in the form of incentive stock options shall not exceed the Initial Limit cumulatively increased on January 1, 2021 and on each January 1 thereafter by the lesser of the Annual Increase for such year or 8,008,734 shares of common stock.

The 2020 Plan will be administered by our compensation committee. Our compensation committee has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of the 2020 Plan. Persons eligible to participate in the 2020 Plan will be those full or part-time officers, employees, non-employee directors and other key persons (including consultants) as selected from time to time by our compensation committee in its discretion.

The 2020 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise price of each option will be determined by our compensation committee but may not be less than 100% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our compensation committee and may not exceed 10 years from the date of grant. Our compensation committee will determine at what time or times each option may be exercised.

Our compensation committee may award stock appreciation rights subject to such conditions and restrictions as it may determine. Stock appreciation rights entitle the recipient to shares of common stock, or cash, equal to the value of the appreciation in our stock price over the exercise price. The exercise price of each stock appreciation right may not be less than 100% of the fair market value of the common stock on the date of grant.

Our compensation committee may award shares of restricted common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and continued employment with us through a specified vesting period. Our compensation committee may also grant shares of common stock that are free from any restrictions under the 2020 Plan. Unrestricted stock may be granted to participants in recognition of past services or other valid consideration and may be issued in lieu of cash compensation due to such participant.

Our compensation committee may grant cash bonuses under the 2020 Plan to participants, subject to the achievement of certain performance goals.

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The 2020 Plan provides that in the case of, and subject to, the consummation of a “sale event” as defined in the 2020 Plan, all outstanding awards may be assumed, substituted or otherwise continued by the successor entity. To the extent that the successor entity does not assume, substitute or otherwise continue such awards, then (i) all stock options and stock appreciation rights will automatically become fully exercisable and the restrictions and conditions on all other awards with time-based conditions will automatically be deemed waived, and awards with conditions and restrictions relating to the attainment of performance goals may become vested and non-forfeitable in connection with a sale event in the compensation committee’s discretion and (ii) upon the effectiveness of the sale event, the 2020 Plan and all awards will automatically terminate. In the event of such termination, (a) individuals holding options and stock appreciation rights will be permitted to exercise such options and stock appreciation rights (to the extent exercisable) prior to the sale event; or (b) we may make or provide for a cash payment to participants holding options and stock appreciation rights equal to the difference between the per share cash consideration payable to stockholders in the sale event and the exercise price of the options or stock appreciation rights (to the extent exercisable).

Our board of directors may amend or discontinue the 2020 Plan and our compensation committee may amend the exercise price of options and amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder’s consent. Certain amendments to the 2020 Plan require the approval of our stockholders.

No awards may be granted under the 2020 Plan after the date that is ten years from the date of stockholder approval. No awards under the 2020 Plan have been made prior to the date of this prospectus. In July 2020, our board of directors approved option grants to purchase an aggregate of 2,909,200 shares of our common stock to certain of our directors, officers and employees contingent and effective upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share in this offering.

2018 Equity Incentive Plan

Our 2018 Equity Incentive Plan, or 2018 Plan, was approved and adopted by our board of directors and stockholders on September 17, 2018. Under the 2018 Plan, we have reserved for issuance an aggregate of 7,033,971 shares of our common stock for the issuance of stock options and other equity awards under the 2018 Plan. This number of shares of common stock reserved for issuance is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization. As of March 31, 2020, options to purchase 48,315 shares of common stock were outstanding under the 2018 Plan. Our board of directors has determined not to make any further awards under the 2018 Plan following the closing of this offering, but all outstanding awards under the 2018 Plan will continue to be governed by their existing terms. The maximum number of shares that may be issued as incentive stock options may not exceed 7,033,971.

The shares of common stock underlying any awards that are forfeited, cancelled, held back upon exercise or settlement of an award to satisfy the exercise price or tax withholding, reacquired by us prior to vesting, satisfied without the issuance of stock, expire or are otherwise terminated (other than by exercise) under the 2018 Plan will be added back to the shares of common stock available for issuance under the 2020 Plan.

Our board of directors has acted as administrator of the 2018 Plan. The administrator has full power to select, from among the individuals eligible for awards, the individuals to whom awards will be granted, to make any combination of awards to participants, and to determine the specific terms and conditions of each award, subject to the provisions of our 2018 Plan. Persons eligible to participate in our 2018 Plan will be those full or part-time officers, employees, non-employee directors, and consultants as selected from time to time by the administrator in its discretion.

Our 2018 Plan permits the granting of both options to purchase common stock intended to qualify as incentive stock options under Section 422 of the Code and options that do not so qualify. The option exercise

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price of each option will be determined by our Committee (as defined in the 2018 Plan) but may not be less than 100% of the fair market value of our common stock on the date of grant, or in the case of an incentive stock option granted to a 10% owner, the exercise price shall not be less than 110% of the fair market value of our common stock on the date of grant. The term of each option will be fixed by our Committee and may not exceed ten years from the date of grant. Our Committee will determine at what time or times each option may be exercised.

Our Committee may award restricted shares of common stock and restricted stock units to participants subject to such conditions and restrictions as it may determine. These conditions and restrictions may include the achievement of certain performance goals and/or continued employment with us through a specified vesting period.

In the event of certain corporate transactions and events, including a reorganization, recapitalization, reclassification, stock dividend, stock split, or other changes to the Company's capital stock, the Committee shall make appropriate adjustments to the maximum number of shares reserved for issuance under the 2018 Plan, the number and kind of securities subject to outstanding awards under the 2018 Plan and the repurchase or exercise price of any outstanding awards under the Plan.

Upon the effective time of a Sale Event (as defined in our 2018 Plan), all outstanding awards granted under our 2018 Plan and our 2018 Plan shall terminate unless assumed by an acquirer or successor entity. In the event of such termination, individuals holding options will be permitted to exercise such options within a specified period of time prior to the Sale Event. With respect to participants holding restricted shares, if such restricted shares are forfeited upon a Sale Event, such restricted shares shall be repurchased by the Company. In addition, in connection with the termination of our 2018 Plan upon a Sale Event, we may make or provide for a payment, in cash or in kind, to participants holding vested and exercisable options or outstanding restricted stock or restricted stock units equal to the difference between (a) the per share cash consideration payable to stockholders in the Sale Event times the number of shares subject to such awards and (b) the aggregate price paid, (or exercise price, as applicable), if any, of the awards. Our board of directors may amend or discontinue our 2018 Plan and our Committee may amend or cancel outstanding awards for purposes of satisfying changes in law or any other lawful purpose, but no such action may adversely affect rights under an award without the holder's consent. Certain amendments to our 2018 Plan require the approval of our stockholders. In July 2020, our board of directors approved option grants to purchase an aggregate of 2,909,200 shares of our common stock to certain of our directors, officers and employees contingent and effective upon the effectiveness of the registration statement of which this prospectus forms a part and with an exercise price equal to the initial public offering price per share in this offering.

No awards may be granted under our 2018 Plan after the date that is ten years from the effective date of our 2018 Plan.

Employee Stock Purchase Plan

On July 2, 2020, our board of directors adopted the Employee Stock Purchase Plan, or the ESPP, and in July 2020, our stockholders approved the ESPP. The ESPP became effective as of the date immediately prior to the date of the effectiveness of the registration statement of which this prospectus is a part. The ESPP is comprised of two components, one of which is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423(b) of the Code and one of which does not so qualify. The ESPP initially reserves and authorizes the issuance of up to a total of 611,354 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2021 and each January 1 thereafter through January 1, 2030, by the least of (i) 1% of the outstanding number of shares of our common stock on the immediately preceding December 31, (ii) 1,222,707 shares or (iii) such number of shares as determined by the ESPP administrator. The number of shares reserved under the ESPP is subject to adjustment in the event of a stock split, stock dividend or other change in our capitalization.

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All employees whose customary employment is for more than 20 hours per week and have completed at least 30 days of employment are eligible to participate in the ESPP. However, any participating employee who would own 5% or more of the total combined voting power or value of all classes of stock after an option were granted under the ESPP would not be eligible to purchase shares under the ESPP.

We will make one or more offerings each year to our employees to purchase shares under the ESPP. The ESPP administrator will determine when offerings will commence and their duration, provided that no offering will exceed 27 months. Each offering may be comprised of one or more purchase periods. Each eligible employee may elect to participate in any offering by submitting an enrollment form at least 15 business days before the relevant offering date.

Each employee who is a participant in the ESPP may purchase shares by authorizing payroll deductions of up to the maximum percentage of his or her base compensation set by the compensation committee during an offering period. Unless the participating employee has previously withdrawn from the offering, his or her accumulated payroll deductions will be used to purchase shares on the last day of the purchase period at a price equal to 85% of the fair market value of the shares on the first day of the offering period or the last day of the purchase period, whichever is lower. An employee may purchase no more than \$25,000 worth of shares of common stock, valued at the start of the purchase period, under the ESPP in any calendar year and may be subject to other limitations set forth in the ESPP.

The accumulated payroll deductions of any employee who is not a participant on the last day of an offering period will be refunded. An employee's rights under the ESPP terminate upon voluntary withdrawal from the plan or when the employee ceases employment with us for any reason.

Additional Narrative Description

401(k) Plan

Our named executive officers are eligible to participate in a tax-qualified retirement plan, or the 401(k) Plan, maintained by our affiliate, ElevateBio Management. Eligible employees are able to defer eligible compensation subject to applicable annual Code limits. Employees' pre-tax or Roth contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. We may make discretionary matching contributions. Employees are immediately and fully vested in their contributions and the Company's matching contributions, if any. The 401(k) Plan is intended to be qualified under Section 401(a) of the Code with the 401(k) Plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) Plan and earnings on those contributions are not taxable to the employees until distributed from the 401(k) Plan.

DIRECTOR COMPENSATION

The following table presents the total compensation for each person who served as a non-employee member of our board of directors and received compensation for such service during the fiscal year ended December 31, 2019. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2019. We reimburse non-employee members of our board of directors for reasonable travel expenses.

Non-Employee Director Compensation Table—2019

Name	Fees Earned or Paid in Cash (\$)	Stock Awards ⁽¹⁾⁽²⁾ (\$)	All Other Compensation (\$)	Total (\$)
Malcolm Brenner	35,000	90,900	—	125,900
Ansbert Gadicke	40,000	90,900	—	130,900
Morana Jovan-Embiricos	26,250	90,900	—	117,150
Juan Vera	—	90,900	150,000 ⁽³⁾	240,900
John Wilson	40,000	90,900	—	130,900

- (1) The amount reported represents the aggregate grant date fair value of the shares of restricted stock awarded to the directors during the 2019 fiscal year, calculated in accordance with Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or ASC, Topic 718. Such grant date fair value does not take into account any estimated forfeitures. The assumptions used in calculating the grant date fair value of the restricted stock units reported in this column are set forth in Note 2 to our audited consolidated financial statements and Note 11 to our interim condensed consolidated financial statements included elsewhere in this prospectus. The amount reported in this column reflects the accounting cost for these restricted stock awards and does not correspond to the actual economic value that may be received by the directors upon the vesting of the shares of restricted stock or any sale of the shares.
- (2) Each director was granted 30,189 shares of restricted stock on June 10, 2019. 25% of the shares subject to each restricted stock award vested on the date of grant, with the remainder vesting in 16 equal quarterly installments thereafter, subject to continued service. Upon a sale event, such restricted stock awards shall accelerate and vest in full. As of December 31, 2019, each director held 19,810 unvested shares of restricted stock.
- (3) Consists of cash compensation pursuant to Mr. Vera's consulting agreement with the Company, which is described below under "Certain Relationships and Related Party Transactions".

Non-Employee Director Compensation Policy

In fiscal year 2019, we paid our non-employee directors who were also not executive officers annual cash retainers, and we granted each of our non-employee directors an equity award, the amounts of which were determined based upon market data. Specifically, each of our non-employee directors who was also not an executive officer was paid an annual cash retainer of \$35,000, prorated to reflect any partial year of service, and each of Dr. Gadicke and Mr. Wilson receive an additional annual retainer of \$5,000 for service on the compensation committee. In addition, each of our non-employee directors, as well as Mr. Vera who was an executive officer, received a restricted stock grant of 30,189 shares.

In connection with this offering, our board of directors will adopt a non-employee director compensation policy, effective upon the effectiveness of the registration statement of which this prospectus forms a part, that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

	Member Annual Fee (\$)	Chairman Additional Annual Fee (\$)
Board of Directors	40,000	30,000
Audit Committee	7,500	15,000
Compensation Committee	5,000	10,000
Nominating and Corporate Governance Committee	4,000	8,000

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In addition, each non-employee director serving on our board of directors who has not previously received an initial option grant prior to completion of this offering and each non-employee director elected or appointed to our board of directors following the completion of this offering will be granted a one-time option to purchase 45,000 shares on the date of such director's election or appointment to the board of directors, which will vest in quarterly installments over three years, subject to continued service through such vesting dates. Each such grant made to a non-employee director currently serving on our board of directors will be made contingent and effective upon the effectiveness of the registration statement of which this prospectus forms a part and will vest from the effective date of grant. On the date of each annual meeting of stockholders of our company, each non-employee director will be granted an annual option to purchase 22,500 shares, which will vest in full of the earlier to occur of the first anniversary of the date of grant or the next annual meeting, subject to continued service as a director through such vesting date. Such awards are subject to full accelerated vesting upon the sale of our company, subject to such director's continued service to us through the date of such sale.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than the compensation agreements and other arrangements described under “Executive Compensation” and “Director Compensation” in this prospectus and the transactions described below, since our conversion into a corporation on September 17, 2018, there has not been and there is not currently proposed, any transaction or series of similar transactions to which we were, or will be, a party in which the amount involved exceeded, or will exceed, \$120,000 and in which any director, executive officer, holder of five percent (5%) or more of any class of our capital stock or any member of the immediate family of, or entities affiliated with, any of the foregoing persons, had, or will have, a direct or indirect material interest.

Sales of Securities

Series A Convertible Preferred Stock Financings

In September 2018, we issued and sold an aggregate of 20,000,000 shares of our Series A2 convertible preferred stock, or the Series A2 Preferred, at a purchase price of \$1.50 per share, pursuant to agreements entered into with investors. Each share of our Series A2 Preferred will automatically convert into one share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series A2 Preferred by related persons:

<u>Participant</u>	<u>Shares of Series A2 Preferred Stock</u>	<u>Total Purchase Price</u>
ElevateBio LLC(1)	\$ 20,000,000	\$ 30,000,000

(1) ElevateBio LLC, is a holder of 5% or more of our capital stock. David Hallal, Vikas Sinha, Morana Jovan Embiricos and Ansbert Gadicke are directors of ElevateBio LLC and also members of our board of directors. David Hallal and Vikas Sinha are also officers of ElevateBio LLC.

In December 2018, we issued and sold an aggregate of 2,066,666 shares of our Series A4 convertible preferred stock, or Series A4 Preferred, at a purchase price of \$1.50 per share, pursuant to agreements entered into with investors. Each share of our Series A4 Preferred will automatically convert into one share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series A4 Preferred by related persons:

<u>Participant</u>	<u>Shares of Series A4 Preferred Stock</u>	<u>Total Purchase Price</u>
Trust Associated with the Hallal Family(1)	1,100,000	\$ 1,650,000
Trust Associated with the Hallal Family(1)	233,333	\$ 350,000

(1) David Hallal is our Chief Executive Officer.

Series A1 to Series A3 Conversion

In May 2019, upon the closing of our Series B Preferred Stock offering and pursuant to our Amended and Restated Certificate of Incorporation, 20,000,000 shares of our Series A1 preferred stock were converted to 22,453,987 shares of Series A3 preferred stock in May 2019. There was no cash consideration for this exchange.

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Series B Convertible Preferred Stock Financing

In May 2019, we sold an aggregate of 14,877,697 shares of our Series B convertible preferred stock, or Series B Preferred, at a purchase price of \$8.15 per share pursuant to agreements entered into with investors. Each share of our Series B Preferred will automatically convert into one share of our common stock immediately prior to the completion of this offering. The following table summarizes purchases of our Series B Preferred by related persons:

Participant	Shares of Series B Preferred Stock	Total Purchase Price
Entities affiliated with F2 Ventures(1)	3,067,483	\$ 24,999,986
Brett Hagen(2)	6,500	\$ 52,975
Jeroen van Beek(3)	10,000	\$ 81,500
Edward Miller(4)	73,619	\$ 599,995

(1) F2 Ventures consists of F2 TPO Investment, LLC, F2 MG Limited and F2 MC, LLC and is a holder of four percent or more of our capital stock. Morana Jovan-Embricos is a Director at F2 Ventures and a member of our board of directors.

(2) Brett Hagen is our Chief Accounting Officer.

(3) Jeroen van Beek is our Chief Commercial Officer.

(4) Edward Miller is our General Counsel.

Redeemable Preferred Stock Redemption Agreement

In September 2018, we entered into a redeemable preferred stock redemption agreement, or Redemption Agreement, to redeem shares of our Series A1 convertible preferred stock held by certain investors, including our executive officer Ann Leen, our director and former executive officer Juan Vera and entities affiliated with our directors John Wilson and Malcolm Brenner (or their affiliates). Pursuant to the Redemption Agreement, for a period of 20 years from the date of the first commercial sale of Viralym-M by us, we are obligated to make earnout payments to such investors on at least an annual basis. The earnout payments will be 10% of our net sales of Viralym-M, which number will be reduced to a high single-digit percentage if certain events occur. Specifically, royalties due to third parties for the sale of Viralym-M are subtracted from the earnout payments due to the investors. Further, if the investors receive at least \$50,000,000 in earnout payments from us during the three-year period after the first commercial sale of Viralym-M, the earnout payment percentage will be reduced.

Amended and Restated Investors' Rights Agreement

In May 2019, we entered into an amended and restated investors' rights agreement with holders of our preferred stock, including our 5% stockholder and entities affiliated with our directors. The investor rights agreement provides these holders the right, following the completion of this offering, to demand that we file a registration statement or request that their shares be covered by a registration statement that we are otherwise filing. The investor rights agreement also provides a right of first refusal to purchase future securities sold by us, which such right shall terminate immediately prior to the consummation of this offering. See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Amended and Restated Voting Agreement

In May 2019, we entered into an amended and restated voting agreement, effective as of May 8, 2019, with certain of our stockholders. Each of ElevateBio and F2 Ventures have appointed representatives to our board of directors. The voting agreement will terminate upon the closing of this offering, and members previously elected to our board of directors pursuant to this agreement will continue to serve as directors until they resign, are removed or their successors are duly elected by the holders of our common stock. The composition of our board of directors after this offering is described in more detail under "Management—Board Composition and Election of Directors."

Amended and Restated Right of First Refusal and Co-Sale Agreement

In May 2019, we entered into an amended and restated right of first refusal and co-sale agreement, effective as of May 9, 2019, with holders of our convertible preferred stock, including some of our 5% stockholders and

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entities affiliated with our directors. The right of first refusal and co-sale agreement provides the key holders the right to purchase all or any portion of transfer stock, as well as the right of co-sale and participation in any proposed transfers. The agreement will terminate upon completion of this offering.

Agreements and Transactions with 5% Stockholders and Their Affiliates

Shared Services Agreements with ElevateBio

We have entered into a shared services agreement, dated as of March 20, 2020, or the Shared Services Agreement, with ElevateBio that provides for ongoing services to us 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. We also have a statement of work to receive manufacturing and project management consulting services from ElevateBio. During the years ended December 31, 2019 and 2018, we incurred an aggregate of \$3.2 million and \$0.2 million, respectively, of expenses related to services provided to us by ElevateBio and its affiliates.

Sublease Agreement with ElevateBio

We have entered into a sublease agreement and related asset rental agreement, each dated as of May 1, 2019, with ElevateBio to sublease certain office space and use certain office equipment in Cambridge, Massachusetts. During the year ended December 31, 2019, we paid ElevateBio an aggregate of \$0.3 million under the sublease agreement, which is included in the \$3.2 million of expenses incurred related to the Shared Services Agreements with ElevateBio discussed above.

Development and Manufacturing Services Agreement with ElevateBio BaseCamp

We are party to a development and manufacturing services agreement, or the BaseCamp Agreement, with BaseCamp, pursuant to which BaseCamp provides us products and services that we use in our laboratory operations, including consulting services, project management services, quality control services and cGMP drug product manufacturing.

During the term of the BaseCamp Agreement, we and BaseCamp may prepare work orders setting forth any products or services to be provided by BaseCamp. Such work orders include applicable specifications, deliverables, timelines, fees and payment schedule. Each work order must be agreed to and signed by both us and BaseCamp, and neither party is obligated to enter into any work order during the term of the agreement. A work order may only be modified by the mutual agreement of both parties.

We and BaseCamp will each retain sole rights to our respective existing intellectual property used in the provision of goods and services under the BaseCamp Agreement. To the extent that new technologies or discoveries are conceived during the course of the BaseCamp Agreement, such technologies or discoveries will be assigned to the party from whose intellectual property such technologies or discoveries were derived. Jointly-derived technologies or discoveries will be jointly owned by BaseCamp and us.

The initial term of the BaseCamp Agreement continues until the later of January 2024 and the date when all services under all work orders have been completed. We may terminate the BaseCamp Agreement in our discretion at any time by giving 90 days' prior written notice to BaseCamp.

Employment Agreements

We have entered into employment agreements with our executive officers. For more information regarding the agreements with our named executive officers, see "Executive Compensation—Employment Agreements."

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Consulting Agreement with Juan Vera

On October 1, 2018, we entered into a consulting agreement with Juan Vera, a member of our board of directors. Pursuant to the consulting agreement, Dr. Vera provides leadership and advice regarding our scientific, clinical, product development and related activities and operations. The consulting agreement was terminated as of July 2, 2020. Pursuant to the consulting agreement, we paid Dr. Vera a consulting fee at a monthly rate of \$12,875, and Dr. Vera was eligible to receive a 35% annual performance bonus subject to approval of our board of directors. Dr. Vera was also entitled to reimbursement for expenses incurred in the course of rendering services under the consulting agreement.

Consulting Agreement with Ann Leen

On October 1, 2018, we entered into a consulting agreement with Ann Leen, a founder and our Chief Scientific Officer. Pursuant to the consulting agreement, Dr. Leen provides services to the Company in her role as Chief Scientific Officer. The consulting agreement, as amended on January 1, 2020, has a term that expires on December 31, 2020, following which the parties may renew the agreement in one-year increments. Pursuant to the consulting agreement, we have agreed to pay Dr. Leen a consulting fee at a monthly rate of \$21,458.33, and Dr. Leen is eligible to receive a 35% annual performance bonus subject to approval of our board of directors. Dr. Leen is also entitled to reimbursement for expenses incurred in the course of rendering services under the consulting agreement.

Director Compensation

See the section titled “Director Compensation” for information regarding compensation of our directors.

Indemnification Agreements

In connection with this offering, we intend to enter into agreements to indemnify our directors and executive officers. These agreements will, among other things, require us to indemnify these individuals for certain expenses (including attorneys’ fees), judgments, fines and settlement amounts reasonably incurred by such person in any action or proceeding, including any action by or in our right, on account of any services undertaken by such person on behalf of our company or that person’s status as a member of our board of directors to the maximum extent allowed under Delaware law.

Directed Share Program

At our request, the underwriters have reserved 5.0% of the shares of common stock offered by this prospectus for sale, at the initial public offering price, to certain of our directors, officers and employees. We do not currently know the extent to which these related persons will participate in the directed share program, if at all. See “Underwriting—Directed share program.”

Policies for Approval of Related Party Transactions

Our board of directors reviews and approves transactions with directors, officers and holders of five percent or more of our voting securities and their affiliates, each a related party. Prior to this offering, the material facts as to the related party’s relationship or interest in the transaction are disclosed to our board of directors prior to their consideration of such transaction, and the transaction is not considered approved by our board of directors unless a majority of the directors who are not interested in the transaction approve the transaction. Further, when stockholders are entitled to vote on a transaction with a related party, the material facts of the related party’s relationship or interest in the transaction are disclosed to the stockholders, who must approve the transaction in good faith.

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In connection with this offering, we expect to adopt a written related party transactions policy that such transactions must be approved by our audit committee. This policy became effective on the date on which the registration statement of which this prospectus is a part is declared effective by the SEC. Pursuant to this policy, the audit committee has the primary responsibility for reviewing and approving or disapproving “related party transactions,” which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed \$120,000 and in which a related person has or will have a direct or indirect material interest. In reviewing any related person transaction, the audit committee will take into account, among other factors that it deems appropriate, whether the related person transaction is on terms no less favorable to us than terms generally available in a transaction with an unaffiliated third-party under the same or similar circumstances, and the extent of the related person’s interest in the related person transaction. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director, or greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and their immediate family members.

PRINCIPAL STOCKHOLDERS

The following table sets forth certain information known to us regarding beneficial ownership of our capital stock as of June 30, 2020, as adjusted to reflect the sale of common stock offered by us in this offering, for:

- each person or group of affiliated persons known by us to be the beneficial owner of more than five percent of our capital stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

To the extent that the underwriters sell more than 16,250,000 shares in this offering, the underwriters have the option to purchase up to an additional 2,437,500 shares at the initial public offering price less the estimated underwriting discounts and commissions.

The following table does not reflect any shares of common stock that may be purchased pursuant to our directed share program described under “Underwriting—Directed Share Program.” If any shares are purchased by our existing principal stockholders, directors or their affiliated entities, the number and percentage of shares of our common stock beneficially owned by them after this offering will differ from those set forth in the following table.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Under those rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power, and includes securities that the individual or entity has the right to acquire, such as through the exercise of stock options, within 60 days of April 30, 2020. Except as noted by footnote, and subject to community property laws where applicable, we believe, based on the information provided to us, that the persons and entities named in the table below have sole voting and investment power with respect to all common stock shown as beneficially owned by them.

The percentage of beneficial ownership prior to this offering in the table below is based on 46,419,373 shares of common stock deemed to be outstanding as of June 30, 2020, assuming the conversion of all outstanding shares of our preferred stock upon the closing of this offering into an aggregate of 39,859,139 shares of common stock upon the closing of this offering, and the percentage of beneficial ownership at this offering in the table below is based on 62,669,373 shares of common stock to be outstanding after the closing of the offering. The information in the table below assumes no exercise of the underwriters’ option to purchase additional shares.

Unless otherwise indicated, the address for each beneficial owner is c/o AlloVir, Inc., 139 Main Street, Suite 500, Cambridge, MA 02142.

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Name and Address of Beneficial Owner	Number of Shares Beneficially Owned Prior to Offering	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
5% Stockholders:			
ElevateBio LLC ⁽¹⁾	13,420,970	28.91%	21.42%
Entities affiliated with Fidelity ⁽²⁾	3,293,489	7.10%	5.26%
Ann Leen ⁽³⁾	2,497,167	5.38%	3.98%
Named Executive Officers and Directors:			
David Hallal ⁽⁴⁾	17,363,754	37.41%	27.71%
Vikas Sinha ⁽⁵⁾	14,227,577	30.65%	22.70%
Jeffrey S. Bornstein	30,197	*	*
Diana Brainard	—	—	—
Malcolm Brenner ⁽⁶⁾	1,048,860	2.26%	1.67%
Ansbert Gadicke ⁽⁷⁾	13,451,167	28.98%	21.46%
Morana Jovan-Embiricos ⁽⁸⁾	15,509,595	33.41%	24.75%
Juan Vera	2,466,970	5.31%	3.94%
John Wilson	5,562,954	11.98%	8.88%
Agustin Melian	531,365	1.14%	*
All Executive Officers and Directors as a group (15 persons)	33,287,778	71.75%	53.14%

* Less than one percent.

- (1) Consists of 13,420,970 shares of our common stock issuable upon conversion of our Series A-2 convertible preferred stock purchased and received by ElevateBio LLC. The mailing address of ElevateBio LLC is 139 Main Street, Suite 500, Cambridge, MA 02142. David Hallal, Vikas Sinha, Morana Jovan-Embiricos and Ansbert Gadicke are directors of ElevateBio LLC. The mailing address of ElevateBio LLC is 139 Main Street, Suite 500, Cambridge, MA 02142.
- (2) Consists of (a) 1,281,457 shares of our common stock issuable upon conversion of our Series B convertible preferred stock purchased and received by Fidelity Contrafund: Fidelity Contrafund, (b) 286,379 shares of our common stock issuable upon conversion of our Series B convertible preferred stock purchased and received by Fidelity Contrafund: Fidelity Contrafund K6, (c) 78,909 shares of our common stock issuable upon conversion of our Series B convertible preferred stock purchased and received by Fidelity Contrafund: Fidelity Contrafund K6, (d) 228,388 shares of our common stock issuable upon conversion of our Series B convertible preferred stock purchased and received by Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund, (e) 822,552 shares of our common stock issuable upon conversion of our Series B convertible preferred stock purchased and received by Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund, and (f) 595,804 shares of our common stock issuable upon conversion of our Series B convertible preferred stock purchased and received by Fidelity Growth Company Commingled Pool By: Fidelity Management Trust Company, as Trustee. The mailing address for Fidelity Contrafund: Fidelity Contrafund, Fidelity Contrafund Commingled Pool, Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund and Fidelity Growth Company Commingled Pool By: Fidelity Management Trust Company, as Trustee is Mag & Co. c/o Brown Brothers Harriman & Co., Attn: Corporate Actions/Vault, 140 Broadway, New York, NY 10005. The mailing address for Fidelity Contrafund: Fidelity Contrafund K6 is The Northern Trust Company, Attn: Trade Securities Processing, 333 South Wabash Ave, 32nd Floor, Chicago, Illinois 60604. The mailing address for Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund is BNY Mellon, One BNY Mellon Center, 500 Grant Street AIM 151-2700, Pittsburgh, PA 15258.
- (3) Consists of (a) 2,436,773 shares of our common stock issuable upon conversion of our Series A-3 convertible preferred stock to the Ann M. Leen Management Trust and (b) 60,394 shares of our common stock to Ann Leen. Dr. Leen is the trustee of the Ann M. Leen Management Trust and may be deemed to beneficially own these securities.
- (4) Consists of (a) 964,388 shares of our common stock to The Hallal Family Irrevocable Trust 2012, (b) 2,083,666 shares of our common stock to David Hallal, (c) 738,153 shares of our common stock issuable upon conversion of our Series A-4 convertible preferred stock purchased and received by Terrie A. Hallal Family Irrevocable Trust 2012, (d) 156,577 shares of our common stock issuable upon conversion of our Series A-2 convertible preferred stock purchased and received by The Hallal Family Irrevocable Trust 2012 and (e) 13,420,970 shares of our common stock issuable upon conversion of our Series A-2 convertible preferred stock purchased and received by ElevateBio LLC. Mr. Hallal is a trustee of the previously listed trusts and may be deemed to beneficially own these securities. Mr. Hallal is the Chairman and Chief Executive Officer of ElevateBio LLC. Mr. Hallal, Vikas Sinha, Ansbert Gadicke and Morana Jovan-Embiricos, members of the board of directors of ElevateBio LLC, may be deemed to have shared voting and investment power over the shares held of record by ElevateBio LLC. Such persons disclaim beneficial ownership of all shares held by ElevateBio LLC except to the extent of any indirect pecuniary interests therein.
- (5) Consists of (a) 806,607 shares of our common stock to Vikas Sinha and (b) 13,420,970 shares of our common stock issuable upon conversion of our Series A-2 convertible preferred stock purchased and received by ElevateBio LLC. Mr. Sinha is a director and the Chief Financial Officer of ElevateBio LLC. 13,420,970 shares of our common stock issuable upon conversion of our Series A-2 shares are owned directly by ElevateBio LLC. Mr. Sinha, David Hallal, Ansbert Gadicke and Morana Jovan-Embiricos, members of the board of directors of ElevateBio LLC, may be deemed to have shared voting and investment power over the shares held of record by ElevateBio LLC. Such persons disclaim beneficial ownership of all shares held by ElevateBio LLC except to the extent of any indirect pecuniary interests therein.

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- (6) Consists of (a) 1,018,663 shares of our common stock issuable upon conversion of our Series A-3 convertible preferred stock purchased and received by Salt Free LP and (b) 30,197 shares of our common stock to Malcolm Brenner. Dr. Brenner has a controlling interest in Salt Free LP and may be deemed to beneficially own these securities.
- (7) Consists of (a) 30,197 shares of our common stock to Ansbert Gadicke and (b) 13,420,970 shares of our common stock issuable upon conversion of our Series A-2 convertible preferred stock purchased and received by ElevateBio LLC. Dr. Gadicke is a director of ElevateBio LLC. 13,420,970 shares of our common stock issuable upon conversion of our Series A-2 shares are owned directly by ElevateBio LLC. Dr. Gadicke, David Hallal, Vikas Sinha and Morana Jovan-Embiricos, members of the board of directors of ElevateBio LLC, may be deemed to have shared voting and investment power over the shares held of record by ElevateBio LLC. Such persons disclaim beneficial ownership of all shares held by ElevateBio LLC except to the extent of any indirect pecuniary interests therein.
- (8) Consists of (a) 247,011 shares of our common stock issuable upon conversion of our Series B convertible preferred stock purchased and received by F2 TPO Investment, LLC, (b) 1,399,732 shares of our common stock issuable upon conversion of our Series B convertible preferred stock purchased and received by F2 MG Limited, (c) 411,685 shares of our common stock issuable upon conversion of our Series B convertible preferred stock purchased and received by F2 MC, LLC, (d) 30,197 shares of our common stock to Morana Jovan-Embiricos and (e) 13,420,970 shares of our common stock issuable upon conversion of our Series A-2 convertible preferred stock purchased and received by ElevateBio LLC. Dr. Jovan-Embiricos is a director of ElevateBio LLC. Dr. Jovan-Embiricos, David Hallal, Vikas Sinha and Ansbert Gadicke, members of the board of directors of ElevateBio LLC, may be deemed to have shared voting and investment power over the shares held of record by ElevateBio LLC. Such persons disclaim beneficial ownership of all shares held by ElevateBio LLC except to the extent of any indirect pecuniary interests therein. The mailing address for F2-TPO Investment, LLC and F2 MC, LLC is c/o Singer McKeon, Inc., 8 West 28th Street, Suite 1001, New York, NY 10018. The mailing address for F2 MG Limited is PO Box 3175, Road Town, Tortola, BVA, with correspondence address at c/o LJ Fiduciary, 8 Rue Saint-Leger, CH 1205, Geneva, Switzerland. Dr. Morana Jovan-Embiricos is a member of our board of directors and is the founding director of Globeways Holdings Limited, which is the appointed manager of each F2 MG Limited, F2-TPO Investments, LLC and F2 MC Limited and makes investment decisions on behalf of such entities with respect to shares held by such entities. Dr. Morana Jovan-Embiricos expressly disclaims beneficial ownership of the securities held by F2 MG Limited, F2-TPO Investments, LLC and F2 MC Limited.

DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our amended and restated certificate of incorporation, which will be effective upon the closing of this offering and amended and restated bylaws, which will be effective on the date of the effectiveness of the registration statement of which this prospectus is a part. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately prior to the completion of this offering. We refer in this section to our amended and restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

General

Upon completion of this offering, our authorized capital stock will consist of 150,000,000 shares of common stock, par value \$0.0001 per share, and 10,000,000 shares of preferred stock, par value \$0.0001 per share, all of which shares of preferred stock will be undesignated.

As of March 31, 2020, 6,559,348 shares of our common stock and 39,859,139 shares of preferred stock were outstanding and held by 107 stockholders of record. This amount does not take into account the conversion of all outstanding shares of our preferred stock into common stock upon the closing of this offering.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

Preferred Stock

Upon the completion of this offering, all outstanding shares of our preferred stock will be converted into shares of our common stock. Upon the consummation of this offering, our board of directors will have the authority, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action. Immediately after consummation of this offering, no shares of preferred stock will be outstanding, and we have no present plan to issue any shares of preferred stock.

Registration Rights

Upon the completion of this offering, the holders of 39,859,139 shares of our common stock, including those issuable upon the conversion of preferred stock will be entitled to rights with respect to the registration of

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these securities under the Securities Act. These rights are provided under the terms of an amended and restated investors' rights agreement between us and holders of our preferred stock. The amended and restated investors' rights agreement includes demand registration rights, short-form registration rights and piggyback registration rights. All fees, costs and expenses of underwritten registrations under this agreement will be borne by us and all selling expenses, including estimated underwriting discounts and selling commissions, will be borne by the holders of the shares being registered.

Demand Registration Rights

Beginning 180 days after the effective date of this registration statement, the holders of 39,859,139 shares of our common stock, including those issuable upon the conversion of preferred stock upon closing of this offering, are entitled to demand registration rights. Under the terms of the amended and restated investors' rights agreement, we will be required, upon the written request of a majority of the holders of registerable securities as defined in the amended and restated investors' rights agreement, to file a registration statement and use best efforts to effect the registration of all or a portion of these shares for public resale at an aggregate price of at least \$50.0 million. We are required to effect only one registration pursuant to this provision of the amended and restated investors' rights agreement.

Short-Form Registration Rights

Pursuant to the amended and restated investors' rights agreement, if we are eligible to file a registration statement on Form S-3, upon the written request of at least a majority of these holders to sell registrable securities at an aggregate price of at least \$25.0 million, we will be required to use commercially reasonable efforts to effect a registration of such shares. We are required to effect only one registration in any twelve-month period pursuant to this provision of the investors' rights agreement. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

Piggyback Registration Rights

Pursuant to the amended and restated investors' rights agreement, if we register any of our securities either for our own account or for the account of other security holders, the holders of these shares are entitled to include their shares in the registration. Subject to certain exceptions contained in the amended and restated investors' rights agreement, we and the underwriters may terminate or withdraw any registration initiated before the effective date of such registration in our sole discretion.

Indemnification

Our amended and restated investors' rights agreement contains customary cross-indemnification provisions, under which we are obligated to indemnify holders of registrable securities in the event of material misstatements or omissions in the registration statement attributable to us, and they are obligated to indemnify us for material misstatements or omissions attributable to them.

Expiration of Registration Rights

The demand registration rights and short form registration rights granted under the investors' rights agreement will terminate on the fifth anniversary of the completion of this offering or at such time after this offering when the holders' shares may be sold without restriction pursuant to Rule 144 within a three-month period.

Anti-Takeover Effects of our Certificate of Incorporation and Bylaws and Delaware Law

Our amended and restated certificate of incorporation and amended and restated bylaws will include a number of provisions that may have the effect of delaying, deferring or preventing another party from acquiring

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control of us and encouraging persons considering unsolicited tender offers or other unilateral takeover proposals to negotiate with our board of directors rather than pursue non-negotiated takeover attempts. These provisions will include the items described below.

Board Composition and Filling Vacancies

Our amended and restated certificate of incorporation will provide for the division of our board of directors into three classes serving staggered three-year terms, with one class being elected each year. Our amended and restated certificate of incorporation will also provide that directors may be removed only for cause and then only by the affirmative vote of the holders of two-thirds or more of the shares then entitled to vote at an election of directors. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of our board, may only be filled by the affirmative vote of a majority of our directors then in office even if less than a quorum. The classification of directors, together with the limitations on removal of directors and treatment of vacancies, has the effect of making it more difficult for stockholders to change the composition of our board of directors.

No Written Consent of Stockholders

Our amended and restated certificate of incorporation will provide that all stockholder actions are required to be taken by a vote of the stockholders at an annual or special meeting, and that stockholders may not take any action by written consent in lieu of a meeting. This limit may lengthen the amount of time required to take stockholder actions and would prevent the amendment of our bylaws or removal of directors by our stockholders without holding a meeting of stockholders.

Meetings of Stockholders

Our amended and restated certificate of incorporation and bylaws will provide that only a majority of the members of our board of directors then in office may call special meetings of stockholders and only those matters set forth in the notice of the special meeting may be considered or acted upon at a special meeting of stockholders. Our amended and restated bylaws will limit the business that may be conducted at an annual meeting of stockholders to those matters properly brought before the meeting.

Advance Notice Requirements

Our amended and restated bylaws establish advance notice procedures with regard to stockholder proposals relating to the nomination of candidates for election as directors or new business to be brought before meetings of our stockholders. These procedures provide that notice of stockholder proposals must be timely given in writing to our corporate secretary prior to the meeting at which the action is to be taken. Generally, to be timely, notice must be received at our principal executive offices not less than 90 days nor more than 120 days prior to the first anniversary date of the annual meeting for the preceding year. Our amended and restated bylaws will specify the requirements as to form and content of all stockholders' notices. These requirements may preclude stockholders from bringing matters before the stockholders at an annual or special meeting.

Amendment to Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Once our amendment and restated certificate of incorporation and amended and restated bylaws are effective, any amendment of our amended and restated certificate of incorporation must first be approved by a majority of our board of directors, and if required by law or our amended and restated certificate of incorporation, must thereafter be approved by a majority of the outstanding shares entitled to vote on the amendment and a majority of the outstanding shares of each class entitled to vote thereon as a class, except that the amendment of the provisions relating to stockholder action, board composition, limitation of liability and the amendment of our amended and restated bylaws and amended and restated certificate of incorporation must be approved by not less than two-thirds of the outstanding shares entitled to vote on the amendment, and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class. Our amended and

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restated bylaws may be amended by the affirmative vote of a majority of the directors then in office, subject to any limitations set forth in the bylaws; and may also be amended by the affirmative vote of a majority of the outstanding shares entitled to vote on the amendment.

Preferred Stock

Our amended and restated certificate of incorporation will provide for 10,000,000 authorized shares of preferred stock. The existence of authorized but unissued shares of preferred stock may enable our board of directors to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our amended and restated certificate of incorporation will grant our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Choice of Forum

Our amended and restated bylaws will 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 will 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 that will become effective upon the completion of this offering will 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 enforceability of similar choice of forum provisions in other companies' certificates of incorporation and bylaws has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable.

Section 203 of the Delaware General Corporation Law

Upon completion of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions:

- before the stockholder became interested, our board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;

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- upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances, but not the outstanding voting stock owned by the interested stockholder; or
- at or after the time the stockholder became interested, the business combination was approved by our board of directors and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, lease, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder; and
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.
- In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Nasdaq Global Select Market Listing

Our common stock has been approved for listing on The Nasdaq Global Select Market under the trading symbol “ALVR.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock will be Computershare Trust Company, N.A. The transfer agent and registrar’s address is 150 Royall Street, Canton, MA 02021.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our shares. Future sales of our common stock in the public market, or the availability of such shares for sale in the public market, could adversely affect market prices prevailing from time to time. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Nevertheless, sales of our common stock in the public market after such restrictions lapse, or the perception that those sales may occur, could adversely affect the prevailing market price at such time and our ability to raise equity capital in the future.

Based on the number of shares outstanding as of July 22, 2020, upon the completion of this offering, 62,669,373 shares of our common stock will be outstanding. Of the outstanding shares, all of the shares sold in this offering will be freely tradable, except that any shares held by our affiliates, as that term is defined in Rule 144 under the Securities Act, may only be sold in compliance with the limitations described below. All remaining shares of common stock held by existing stockholders immediately prior to the completion of this offering will be “restricted securities” as such term is defined in Rule 144. These restricted securities were issued and sold by us, or will be issued and sold by us, in private transactions and are eligible for public sale only if registered under the Securities Act or if they qualify for an exemption from registration under the Securities Act, including the exemptions provided by Rule 144 or Rule 701, summarized below.

Rule 144

In general, a person who has beneficially owned restricted stock for at least six months would be entitled to sell their securities provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Securities Exchange Act of 1934, as amended, or the Exchange Act, periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three-month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares then outstanding, which will equal approximately 626,694 shares immediately after this offering, assuming no exercise of the underwriters’ option to purchase additional shares, based on the number of shares outstanding as of July 22, 2020; or
- the average weekly trading volume of our common stock on The Nasdaq Global Select Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares.

However, substantially all Rule 701 shares are subject to lock-up agreements as described below and under “Underwriting” included elsewhere in this prospectus and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

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Lock-Up Agreements

We, our directors and executive officers and holders of substantially all of our capital stock have signed a lock-up agreement that prevent us and them from selling any of our common stock or any securities convertible into or exercisable or exchangeable for common stock for a period of not less than 180 days from the date of this prospectus without the prior written consent of Morgan Stanley & Co. LLC, J.P Morgan Securities LLC and SVB Leerink LLC, subject to certain exceptions. See the section entitled “Underwriting” appearing elsewhere in this prospectus for more information.

Registration Rights

Upon completion of this offering, certain holders of our securities will be entitled to various rights with respect to registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in these shares becoming fully tradable without restriction under the Securities Act immediately upon the effectiveness of the registration. See the section entitled “Description of Capital Stock—Registration Rights” appearing elsewhere in this prospectus for more information.

Equity Incentive Plans

We intend to file one or more registration statements on Form S-8 under the Securities Act to register our shares issued or reserved for issuance under our equity incentive plans. The first such registration statement is expected to be filed soon after the date of this prospectus and will automatically become effective upon filing with the SEC. Accordingly, shares registered under such registration statement will be available for sale in the open market, unless such shares are subject to vesting restrictions with us or the lock-up restrictions described above. As of the date of this prospectus, we estimate that such registration statement on Form S-8 will cover approximately 8,718,731 shares.

**MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR
NON-U.S. HOLDERS OF COMMON STOCK**

The following discussion is a summary of certain material U.S. federal income tax considerations applicable to non-U.S. holders (as defined below) with respect to their ownership and disposition of shares of our common stock issued pursuant to this offering. For purposes of this discussion, a non-U.S. holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes:

- a non-resident alien individual;
- a foreign corporation or any other foreign organization taxable as a corporation for U.S. federal income tax purposes; or
- a foreign estate or trust, the income of which is not subject to U.S. federal income tax on a net income basis.

This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common stock through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock through a partnership or other pass-through entity, as applicable.

This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus and, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or differing interpretation could alter the tax consequences to non-U.S. holders described in this prospectus. There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We assume in this discussion that a non-U.S. holder holds shares of our common stock as a capital asset within the meaning of Section 1221 of the Code, which is generally property held for investment.

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances nor does it address any U.S. state, local or non-U.S. taxes, the alternative minimum tax, the Medicare tax on net investment income, the rules regarding qualified small business stock within the meaning of Section 1202 of the Code, or any other aspect of any U.S. federal tax other than the income tax. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt or governmental organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- pension plans;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- "qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";
- persons deemed to sell our common stock under the constructive sale provisions of the Code;

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- persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

This discussion is for general information only and is not tax advice. Accordingly, all prospective non-U.S. holders of our common stock should consult their tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock.

Distributions on Our Common Stock

As described in the section entitled “Dividend Policy,” we do not anticipate declaring or paying dividends to holders of our common stock in the foreseeable future. Distributions, if any, on our common stock will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder’s investment, up to such holder’s tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in “Gain on Sale or Other Taxable Disposition of Our Common Stock.” Any such distributions will also be subject to the discussions below under the sections titled “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements—FATCA.”

Subject to the discussion in the following two paragraphs in this section, dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States, are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. However, such U.S. effectively connected income, net of specified deductions and credits, is taxed at the same regular U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional “branch profits tax” at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence.

A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder’s country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) to the applicable withholding agent and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for such lower rate of U.S. withholding tax as may be specified under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing a U.S. tax return with the IRS.

Gain on Sale or Other Taxable Disposition of Our Common Stock

Subject to the discussions below under “Backup Withholding and Information Reporting” and “Withholding and Information Reporting Requirements—FATCA,” a non-U.S. holder generally will not be subject to any U.S. federal income or withholding tax on any gain realized upon such holder’s sale or other taxable disposition of shares of our common stock unless:

- the gain is effectively connected with the non-U.S. holder’s conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a permanent establishment or a fixed-base

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maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on a net income basis at the regular U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in “Distributions on Our Common Stock” also may apply;

- the non-U.S. holder is a nonresident alien individual who is present in the United States for a period or periods aggregating 183 days or more in the taxable year of the disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder’s country of residence) on the net gain derived from the disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been, at any time during the five-year period preceding such sale or other taxable disposition (or the non-U.S. holder’s holding period, if shorter) a “U.S. real property holding corporation,” unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the 5-year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Backup Withholding and Information Reporting

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on our common stock paid to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above in “Distributions on Our Common Stock,” generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding will generally apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker.

Non-U.S. holders should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them. Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement. Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder’s U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS in a timely manner.

Withholding and Information Reporting Requirements—FATCA

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a U.S. federal withholding tax at a rate of 30% on payments of dividends on our common stock paid to a foreign entity unless (i) if the foreign entity is a “foreign financial institution,” such foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the foreign entity is not a “foreign financial institution,” such foreign entity identifies certain of its U.S. investors, if any, or (iii) the foreign entity is otherwise exempt under FATCA. Such withholding may also apply to payments of proceeds of sales or other dispositions of our common stock, although under proposed regulations (the preamble to which specifies that taxpayers are permitted to rely on them pending finalization), no withholding will apply to payments of gross proceeds. Under certain circumstances, a non-U.S. holder may be eligible for refunds or credits of this withholding tax. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Non-U.S. holders should consult their tax advisors regarding the possible implications of this legislation on their investment in our common stock and the entities through which they hold our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

UNDERWRITING

Under the terms and subject to the conditions in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom Morgan Stanley & Co. LLC, J.P. Morgan Securities LLC and SVB Leerink LLC are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of shares indicated below:

<u>Name</u>	<u>Number of Shares</u>
Morgan Stanley & Co. LLC	5,687,500
J.P. Morgan Securities LLC	5,687,500
SVB Leerink LLC	3,087,500
Piper Sandler & Co.	1,787,500
Total:	<u>16,250,000</u>

The underwriters and the representatives are collectively referred to as the “underwriters” and the “representatives” respectively. The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters’ over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$0.71400 per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 2,437,500 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter’s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase up to an additional 2,437,500 shares of common stock.

	<u>Per Share</u>	<u>Total</u>	
		<u>No Exercise</u>	<u>Full Exercise</u>
Public offering price	\$ 17.00	\$ 276,250,000	\$ 317,687,500
Underwriting discounts and commissions to be paid by us	\$ 1.19	\$ 19,337,500	\$ 22,238,125
Proceeds, before expenses, to us	\$ 15.81	\$ 256,912,500	\$ 295,449,375

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The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$3,000,000. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority up to \$30,000.

The underwriters have informed us that they do not intend sales to discretionary accounts to exceed 5% of the total number of shares of common stock offered by them.

Our common stock has been approved for listing on the The Nasdaq Global Select Market under the trading symbol “ALVR”.

We and all directors and officers and the holders of substantially all of our outstanding stock and stock options have agreed that, without the prior written consent of Morgan Stanley & Co. LLC, J.P Morgan Securities LLC and SVB Leerink LLC, on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus (the “restricted period”):

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock;
- file any registration statement with the Securities and Exchange Commission relating to the offering of any shares of common stock or any securities convertible into or exercisable or exchangeable for common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the common stock;

whether any such transaction described above is to be settled by delivery of common stock or such other securities, in cash or otherwise. In addition, we and each such person agrees that, without the prior written consent of Morgan Stanley & Co. LLC, J.P Morgan Securities LLC and SVB Leerink LLC on behalf of the underwriters, we or such other person will not, during the restricted period, make any demand for, or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock.

The restrictions described in the immediately preceding paragraph do not apply to:

- transactions relating to shares of common stock or other securities acquired in the this offering or in open market transactions after the pricing of the this offering, *provided* that, with respect to certain stockholders, no filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made in connection with subsequent sales of common stock or other securities acquired in this offering or in such open market transactions;
- transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock as a bona fide gift, or to a charitable organization or educational institution in a transfer not involving a disposition for value, provided that (i) each transferee, donee or distributee shall sign and deliver a lock-up letter substantially in the form of this letter and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock;
- transfers or dispositions of shares of common stock or any security convertible into or exercisable or exchangeable for common stock to any member of the immediate family of such person or any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned in a transaction not involving a disposition for value, provided that (i) each transferee, donee or distributee shall sign and deliver a lock-up letter substantially in the form of this letter and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock;

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- distributions of shares of common stock or any security convertible into common stock to general or limited partners, members, beneficiaries or other equityholders of the undersigned, its direct or indirect affiliates (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) or to an investment fund or other entity that controls or manages, or is under common control with, the undersigned, provided that (i) each transferee, donee or distributee shall sign and deliver a lock-up letter substantially in the form of this letter and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock;
- transfers or dispositions of shares of common stock or any security convertible into or exercisable or exchangeable for common stock (i) by will, other testamentary document or intestate succession to the legal representative, heir, beneficiary or a member of the immediate family of the undersigned upon the death of the undersigned or (ii) by operation of law pursuant to orders of a court or regulatory agency, in connection with a negotiated divorce settlement or pursuant to a qualified domestic relations order, , provided that (i) each transferee, donee or distributee shall sign and deliver a lock-up letter substantially in the form of this letter and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, other than any Form 4 or Form 5 required to be filed under the Exchange Act if the undersigned is subject to Section 16 reporting with respect to the company under the Exchange Act, any such filing will indicate by footnote disclosure or otherwise the nature of the transfer or disposition;
- transfers or dispositions of shares of common stock or any security convertible into or exercisable or exchangeable for common stock to the company pursuant to any contractual arrangement in effect on the date of this agreement and disclosed to the underwriters in writing that provides for the repurchase of the undersigned's common stock or other securities by the company or in connection with the termination of the undersigned's employment with or service to the company; *provided* that any filing under Section 16(a) of the Exchange Act reporting a reduction in beneficial ownership of common stock shall indicate by footnote disclosure or otherwise the nature of the transfer or disposition);
- transfers or dispositions of shares of common stock or other securities to the company in connection with the conversion of any convertible security into, or the exercise of any option or warrant for, shares of common stock (including by way of "net" or "cashless" exercise solely to cover withholding tax obligations in connection with such exercise or transfer to the company for the payment of taxes as a result of such exercise); *provided* that (i) any such shares of common stock received by the undersigned shall be subject to the terms of this agreement and (ii) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, shall be voluntarily made during the restricted period and (iii) to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of such transfers or dispositions pursuant to this provision, it shall clearly indicate that the filing relates to the circumstances described in this provision;
- the establishment of a trading plan on behalf of a shareholder, officer or director of the company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock, *provided* that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of the undersigned or the company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period. In addition, the undersigned agrees that, without the prior written consent of Morgan Stanley & Co. LLC, J.P Morgan Securities LLC and SVB Leerink LLC, it will not, during the restricted period, make any demand for or exercise any right with respect to, the registration of any shares of common stock or any security convertible into or exercisable or exchangeable for common stock. The undersigned also agrees and consents to the entry of stop transfer instructions with the company's transfer agent and registrar against the transfer of the undersigned's shares of common stock except in compliance with the foregoing restrictions; or
- (i) transfers of shares of common stock (or any securities convertible into or exercisable or exchangeable for common stock) pursuant to a bona fide third-party tender offer for shares of the

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company's capital stock made to all holders of the company's securities, merger, consolidation or other similar transaction approved by the company's board of directors the result of which is that any person (as defined in Section 13(d)(3) of the Exchange Act), or group of persons, other than the company, becomes the beneficial owner (as defined in Rules 13d-3 and 13d-5 of the Exchange Act) of more than 50% of the total voting power of the voting stock of the company and (ii) entry into any lock-up, voting or similar agreement pursuant to which the undersigned may agree to transfer, sell, tender or otherwise dispose of shares of common stock or such other securities in connection with a transaction described in (i) above; provided that in the event that such change of control transaction is not completed, the shares of common stock (or any security convertible into or exercisable or exchangeable for common stock) owned by the undersigned shall remain subject to the restrictions contained in this agreement, provided that (a) each transferee, donee or distributee shall sign and deliver a lock-up letter substantially in the form of this letter and (b) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock.

Morgan Stanley & Co. LLC, J.P Morgan Securities LLC and SVB Leerink LLC, in their sole discretion, may release the common stock and other securities subject to the lock-up agreements described above in whole or in part at any time.

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in this offering. As an additional means of facilitating this offering, the underwriters may bid for, and purchase, shares of common stock in the open market to stabilize the price of the common stock. These activities may raise or maintain the market price of the common stock above independent market levels or prevent or retard a decline in the market price of the common stock. The underwriters are not required to engage in these activities and may end any of these activities at any time.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed, and may in the future perform, various financial advisory and investment banking services for us, for which they received or will receive customary fees and expenses.

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related

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derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

Directed Share Program

Furthermore, at our request, the underwriters have reserved 5.0% of the shares of common stock offered by this prospectus for sale, at the initial public offering price, to certain of our directors, officers and employees. Any reserved shares purchased by our directors and officers will be subject to a 180-day lock-up described above. The sales will be made at our direction by Fidelity Capital Markets, a division of National Financial Services LLC, an entity affiliated with Fidelity Management & Research Company, or FMR, through a directed share program. The number of shares of common stock available for sale to the general public will be reduced by the number of reserved shares sold to these individuals. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares of common stock offered by this prospectus.

Pricing of the Offering

Prior to this offering, there has been no public market for our common stock. The initial public offering price was determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price were our future prospects and those of our industry in general, our sales, earnings and certain other financial and operating information in recent periods, and the price-earnings ratios, price-sales ratios, market prices of securities, and certain financial and operating information of companies engaged in activities similar to ours.

Selling Restrictions

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit

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prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

European Economic Area and the United Kingdom

In relation to each Member State of the European Economic Area and the United Kingdom (each, a "Relevant State"), no securities have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the securities which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of securities may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined under the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation, provided that no such offer of shares shall require us or any of our representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129 (as amended).

United Kingdom

Each underwriter has represented and agreed that:

- (a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act 2000 ("FSMA") received by it in connection with the issue or sale of the shares of our common stock in circumstances in which Section 21(1) of the FSMA does not apply to us; and
- (b) it has complied and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the shares of our common stock in, from or otherwise involving the United Kingdom.

Hong Kong

Shares of our common stock may not be offered or sold by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder or (iii) in other circumstances which

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do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap.32, Laws of Hong Kong), and no advertisement, invitation or document relating to shares of our common stock may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap.571, Laws of Hong Kong) and any rules made thereunder.

Japan

No registration pursuant to Article 4, paragraph 1 of the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) (the “FIEL”) has been made or will be made with respect to the solicitation of the application for the acquisition of the shares of common stock.

Accordingly, the shares of common stock have not been, directly or indirectly, offered or sold and will not be, directly or indirectly, offered or sold in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan) or to others for re-offering or re-sale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan except pursuant to an exemption from the registration requirements, and otherwise in compliance with, the FIEL and the other applicable laws and regulations of Japan.

For Qualified Institutional Investors (“QII”)

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a “QII only private placement” or a “QII only secondary distribution” (each as described in Paragraph 1, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred to QIIs.

For Non-QII Investors

Please note that the solicitation for newly-issued or secondary securities (each as described in Paragraph 2, Article 4 of the FIEL) in relation to the shares of common stock constitutes either a “small number private placement” or a “small number private secondary distribution” (each as is described in Paragraph 4, Article 23-13 of the FIEL). Disclosure regarding any such solicitation, as is otherwise prescribed in Paragraph 1, Article 4 of the FIEL, has not been made in relation to the shares of common stock. The shares of common stock may only be transferred en bloc without subdivision to a single investor.

Singapore

This prospectus supplement and the accompanying prospectus have not been and will not be registered as a prospectus with the Monetary Authority of Singapore under the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”). Accordingly, each underwriter has not offered or sold any shares or caused such shares to be made the subject of an invitation for subscription or purchase and will not offer or sell such shares or cause such shares to be made the subject of an invitation for subscription or purchase, and has not circulated or distributed, nor will it circulate or distribute, this prospectus supplement, the accompanying prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of such shares, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions, specified in Section 275, of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

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Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is: (a) a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or (b) a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor, securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), or to any person arising from an offer referred to in Section 275(1A), or Section 276(4)(i)(B) of the SFA; (2) where no consideration is or will be given for the transfer; (3) where the transfer is by operation of law; (4) as specified in Section 276(7) of the SFA; or (5) as specified in Regulation 37A of the Securities and Futures (Offers of Investments) (Securities and Securities-based Derivatives Contracts) Regulations 2018 of Singapore.

Singapore SFA Product Classification—In connection with Section 309B of the SFA and the Securities and Futures (Capital Markets Products) Regulations 2018 (the “CMP Regulations 2018”), the Company has determined, and hereby notifies all relevant persons (as defined in the CMP Regulations 2018), that the shares are “prescribed capital markets products” (as defined in the CMP Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).

LEGAL MATTERS

The validity of the shares of common stock offered by this prospectus will be passed upon for us by Goodwin Procter LLP, Boston, Massachusetts. Certain legal matters related to this offering will be passed upon for the underwriters by Latham & Watkins LLP, New York, New York.

EXPERTS

The financial statements as of December 31, 2019 and 2018, and for each of the two years in the periods then ended, included in this Prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein (which report expresses an unqualified opinion on the financial statements and includes an explanatory paragraph referring to the adoption of Financial Accounting Standards Board, Accounting Standards Codification 842, *Leases*). Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the common stock we are offering by this prospectus. This prospectus does not contain all of the information included in the registration statement. For further information pertaining to us and our common stock, you should refer to the registration statement and to its exhibits. Whenever we make reference in this prospectus to any of our contracts, agreements or other documents, the references are not necessarily complete, and you should refer to the exhibits attached to the registration statement for copies of the actual contract, agreement or other document.

Upon the completion of the offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at www.AlloVir.com. The information contained in or accessible from our website is not incorporated into this prospectus, and you should not consider it part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

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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, 2019 and 2018, the related consolidated statements of operations and comprehensive loss, members’ interests, convertible preferred stock and changes in members’ and stockholders’ deficit, and cash flows, for each of the two years in the period ended December 31, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, effective January 1, 2019, the Company adopted Financial Accounting Standards Board, Accounting Standards Codification Topic 842, *Leases*, using the modified retrospective transition approach, as applied to the earliest comparative period presented.

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

June 3, 2020 (July 23, 2020, as to the effects of the reverse stock split described in Note 19)

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

ALLOVIR, INC.
CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)	December 31,	
Assets	2019	2018
Current assets:		
Cash and cash equivalents	\$ 61,084	\$ 22,199
Restricted cash	—	2,761
Short-term investments	64,993	—
Accrued interest	262	—
Unbilled grant receivables	298	202
Subscription receivable	—	100
Prepaid expenses and other current assets	676	51
Total current assets	127,313	25,313
Property and equipment, net	350	—
Operating lease right-of-use assets	11,759	—
Other assets	—	6
Total assets	\$139,422	\$ 25,319
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	\$ 630	\$ 153
Accrued expenses	5,163	674
Deferred grant revenue	—	2,663
Operating lease liability, current	3,067	—
Amount due to related party	246	247
Total current liabilities	9,106	3,737
Operating lease liability, long term	8,692	—
Total liabilities	17,798	3,737
Commitments and contingencies (Note 16)		
Series B preferred stock, \$0.0001 par value: 14,877,697 shares authorized, issued and outstanding, net of issuance costs (liquidation value of \$121.3 million)	120,923	—
Series A preferred stock, \$0.0001 par value: 64,520,653 and 88,733,334 shares authorized at December 31, 2019 and 2018, respectively; 44,520,653 and 42,066,666 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively; net of issuance costs (liquidation value of \$66.8 million)	52,204	52,204
Stockholders' deficit:		
Common stock, \$0.0001 par value: 90,000,000 and 96,500,000 shares authorized at December 31, 2019 and 2018, respectively; 6,502,929 and 4,118,077 shares issued at December 31, 2019 and December 31, 2018, respectively; 2,099,740 and 747,231 shares outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Additional paid-in capital	3,748	858
Accumulated other comprehensive income	68	—
Accumulated deficit	(55,319)	(31,480)
Total stockholders' deficit	(51,503)	(30,622)
Total liabilities, convertible preferred stock and stockholders' deficit	\$139,422	\$ 25,319

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

ALLOVIR, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)	Years Ended December 31,	
	2019	2018
Revenue	\$ 165	\$ 1,135
Operating expenses:		
Research and development	16,248	1,700
General and administrative	10,618	3,031
Total operating expenses	26,866	4,731
Loss from operations	(26,701)	(3,596)
Total other income, net:		
Interest income	2,065	56
Other income, net	797	1,110
Net loss	(23,839)	(2,430)
Deemed dividend	—	(5,726)
Net loss attributable to common stockholders	\$ (23,839)	\$ (8,156)
Net loss per share attributable to common stockholders – basic and diluted*	\$ (18.54)	\$ (37.36)
Weighted-average common shares outstanding – basic and diluted*	1,285,933	204,431
Pro forma net loss per share attributable to common stockholders – basic and diluted (unaudited)	\$ (0.64)	
Pro forma weighted-average common shares outstanding – basic and diluted (unaudited)	37,098,341	
Comprehensive loss:		
Net loss	\$ (23,839)	\$ (2,430)
Other comprehensive income, net of tax:		
Unrealized gain on available-for-sale securities	68	—
Total other comprehensive income	68	—
Comprehensive loss	\$ (23,771)	\$ (2,430)

* Net loss per share attributable to common stockholders and weighted average common shares outstanding is presented for the period from September 17, 2018 through December 31, 2018 using a net loss attributable to common stockholders of \$7,637. See Note 15.

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

ALLOVIR, INC.
**CONSOLIDATED STATEMENTS OF MEMBERS' INTEREST, CONVERTIBLE PREFERRED STOCK AND CHANGES IN MEMBERS'
AND STOCKHOLDERS' DEFICIT**

(in thousands, except share amounts)	<u>Class C Preferred</u>	<u>Class D Preferred</u>	<u>Series B Preferred Stock</u>		<u>Series A Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-In Capital</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Deficit</u>
	<u>Amount</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Balance at December 31, 2017	\$ 2,264	\$ 1,321	—	\$ —	—	\$ —	—	\$ —	\$ 203	—	\$ (3,582)	\$ (3,379)
Conversion of ViraCyte LLC Membership Interests for ViraCyte, Inc Series A1 Preferred Stock upon LLC Conversion	(1,864)	(719)	—	—	17,200,000	15,164	—	—	—	—	(12,582)	(12,582)
Conversion of ViraCyte LLC Profits Interest for ViraCyte, Inc. Series A1 Preferred Stock upon LLC Conversion	—	—	—	—	2,800,000	4,200	—	—	—	—	(4,200)	(4,200)
Issuance of Redeemable Preferred Stock, recognition of deemed dividend and repurchase of Class B membership interests upon LLC Conversion	(400)	(602)	—	—	6,666,666	—	—	—	(203)	—	(8,686)	(8,889)
Issuance of Series A2 Preferred Stock, net of \$225 issuance costs	—	—	—	—	20,000,000	29,775	—	—	—	—	—	—
Issuance of Series A4 Preferred Stock, net of \$35 issuance costs	—	—	—	—	2,066,666	3,065	—	—	—	—	—	—
Redemption of Redeemable Preferred Stock	—	—	—	—	(6,666,666)	—	—	—	—	—	—	—
Issuance of common stock, upon vesting of restricted stock	—	—	—	—	—	—	747,231	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	—	—	858	—	—	858
Net loss	—	—	—	—	—	—	—	—	—	—	(2,430)	(2,430)
Balance at December 31, 2018	<u>\$ —</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>42,066,666</u>	<u>\$52,204</u>	<u>747,231</u>	<u>\$ —</u>	<u>\$ 858</u>	<u>\$ —</u>	<u>\$ (31,480)</u>	<u>\$ (30,622)</u>

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

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ALLOVIR, INC.
**CONSOLIDATED STATEMENTS OF MEMBERS' INTEREST, CONVERTIBLE PREFERRED STOCK AND CHANGES IN MEMBERS'
AND STOCKHOLDERS' DEFICIT (Continued)**

(in thousands, except share amounts)	Class C Preferred	Class D Preferred	Series B Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Deficit
	Amount	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
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	<u>\$ —</u>	<u>\$ —</u>	<u>14,877,697</u>	<u>\$120,923</u>	<u>44,520,653</u>	<u>\$52,204</u>	<u>2,099,740</u>	<u>\$ —</u>	<u>\$ 3,748</u>	<u>\$ 68</u>	<u>\$(55,319)</u>	<u>\$ (51,503)</u>

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,	
	2019	2018
Cash flows from operating activities		
Net loss	\$ (23,839)	\$ (2,430)
Adjustments to reconcile net loss to net cash (used in) provided by operating activities:		
Depreciation and amortization	19	—
Accretion of discounts on short-term investments	(620)	—
Stock compensation expense	2,890	967
Changes in operating assets and liabilities:		
Subscription receivable and unbilled grant receivables	4	170
Accrued interest	(262)	—
Prepaid expenses and other current assets	(620)	(28)
Accounts payable, accrued expenses and amount due to related party	4,936	601
Deferred grant revenue	(2,663)	2,663
Net cash (used in) provided by operating activities	(20,155)	1,943
Cash flows from investing activities		
Purchase of property and equipment	(339)	—
Purchase of short-term investments	(119,305)	—
Maturities of short-term investments	55,000	—
Net cash used in investing activities	(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)	(128)
Proceeds from issuance of Series A2 Preferred Stock	—	30,000
Proceeds from issuance of Series A4 Preferred Stock	—	3,000
Redemption of Redeemable Preferred Stock	—	(10,000)
Net cash provided by financing activities	120,923	22,872
Net increase in cash, cash equivalents and restricted cash	36,124	24,815
Cash, cash equivalents, and restricted cash at beginning of period	24,960	145
Cash, cash equivalents, and restricted cash at end of period	\$ 61,084	\$ 24,960
Non-cash investing and financing activities		
Unrealized gain on short-term investments	68	—
Right-of-use assets obtained in exchange for operating lease liability	13,213	—
Purchase of property and equipment included in accounts payable	30	—
Issuance of Series A3 Preferred Stock related to anti-dilution rights	3,681	—
Deferred financing costs for Series A2 Preferred Stock and Series A4 Preferred Stock in accrued expenses at year end	—	132
Deemed dividend and repurchase of Class B membership interests	—	8,889
Receivables related to subscription receivables for Series A4 Preferred Stock issuance	—	100
Conversion of Class A, Class C and Class D membership interests to preferred stock	—	3,585
Conversion of Class B membership interests to preferred stock	—	12,582
Conversion of LLC profits interests to preferred stock	—	4,200
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 late clinical-stage cell therapy company focused on developing allogeneic, off-the-shelf multi-virus specific T cell (“VST”) therapies to prevent and treat severe viral-associated diseases. AlloVir is built upon a technology platform to restore natural immune defenses in immunocompromised patients. AlloVir’s lead asset, Viralym-M has completed a Phase 2 clinical trial for the treatment of cytomegalovirus (“CMV”), adenovirus (“AdV”), BK virus (“BKV”), human herpesvirus 6 (“HHV-6”), and Epstein-Barr virus (“EBV”) associated conditions in drug refractory patients post-allogeneic hematopoietic stem-cell transplant (“HSCT”).

The Company is planning to initiate numerous clinical trials in the 2nd half of 2020 to treat viral complications in both HSCT and solid organ transplant (“SOT”) immunocompromised patient populations. In HSCT, Phase 3 clinical trials will include the treatment of BKV-associated Hemorrhagic Cystitis AdV, and CMV; a Phase 2 multivirus (CMV, BKV, EBV, AdV and HHV-6 trial is being planned; and a SOT trial investigating Viralym-M among patients with BK-nephropathy. Additionally, a second multi-virus specific T cell therapy targeting common respiratory viral pathogens (respiratory syncytial virus (“RSV”), influenza, human metapneumovirus (“hMPV”), and parainfluenza (“PIV”)) to enter Phase 1 studies in the second half of 2020.

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 (the “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.

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 (Note 11). 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 12 for further discussion). The Chief Executive Officer, Chief Financial Officer, and other executives of ElevateBio also serve in similar management roles at AlloVir.

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

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

1. Nature of the Business (Continued)

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 Company believes that its \$61.1 million of cash and cash equivalents and \$65.0 million of short-term investments held at December 31, 2019, 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 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, 2019, the Company has funded its operations primarily with proceeds received from capital contributions, 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 \$23.8 million for the year ended December 31, 2019 and \$8.2 million for the year ended December 31, 2018. In addition, at December 31, 2019, the Company had an accumulated deficit of \$55.3 million. The Company expects to continue to generate operating losses for the foreseeable future.

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.

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.

Reclassification

Certain reclassifications have been made to the 2018 consolidated financial statements to conform with the 2019 consolidated financial statement presentation. Accounts receivable of approximately \$18,000 was reclassified and included within prepaid expenses and other current assets in the consolidated balance sheet at December 31, 2018. The change in amount due to related party of approximately \$26,000 was regrouped and presented within the change in accounts payable and accrued expenses in the 2018 consolidated statement of cash flows.

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

2. Summary of Significant Accounting Policies (Continued)

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 U.S. treasury securities, money market funds and demand deposits.

Restricted Cash

Cash accounts with any type of restriction are classified as restricted cash. At December 31, 2018, the Company held cash of \$2.8 million in a separate restricted bank account related to the receipt of proceeds from the Company's grant agreements (Note 9). The Company classified this amount as current restricted cash in the accompanying consolidated balance sheet at December 31, 2018. Prior to December 31, 2019, the Company returned the balance of the restricted cash to the grant provider.

Short-Term Investments

Short-term investments consist of U.S. treasury securities (one class) 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, 2019.

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

2. Summary of Significant Accounting Policies (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 (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, 2019 and 2018.

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.

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

2. Summary of Significant Accounting Policies (Continued)

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, restricted cash, 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.

Deferred Offering Costs

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are presented in the consolidated balance sheets as a direct reduction from the carrying amount of the respective equity instrument issued. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. At December 31, 2019 and 2018, the Company recorded deferred offering costs of \$0.1 million and \$0.3 million, respectively.

Revenue Recognition

The Company's sole source of revenue in 2019 and 2018 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

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

2. Summary of Significant Accounting Policies (Continued)

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 Vivalym-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).

Other Income, Net

The Company records other government grants, not considered customers under ASC 606, in Other Income 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 revenue 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

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

2. Summary of Significant Accounting Policies (Continued)

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 we have determined that the grantor is a customer, are presented in the consolidated statements of operations and comprehensive loss as revenue or other income.

Profits Interest Compensation Expense

Prior to September 17, 2018, the Company periodically granted profits interests to employees and non-employees. The profits interests represented a separate substantive class of equity with defined rights within the Limited Liability Company Agreement ("LLC Agreement"). The profits interests in the Company represent an interest in the increase in the value of the entity over the Distribution Threshold and as determined at the time of grant. The Distribution Threshold for each profits interest grant reflects an amount that equals or exceeds the fair market value of the Company as of the date the profits interest is granted. The specified Distribution Threshold includes the cumulative capital contributions and net profits for the Company. The holder, therefore, had the right to participate in distributions of profits only in excess of the Distribution Threshold. The Distribution Threshold was based on the valuation of the common unit on the grant date.

The Company accounted for profits interests granted in accordance with ASC 505-50, *Equity-Based Payments to Non-Employees* ("ASC 505-50").

The valuation methodology employed by the Company includes various assumptions, including the expected life of profits interests using the simplified method, the expected volatility and the expected risk-free interest rate. These assumptions reflected the Company's best estimates, but they involve inherent uncertainties based on market conditions generally outside the control of the Company.

Stock-Based Compensation Expense

The Company grants restricted stock and stock options to employees, consultants and directors. The Company records stock-based compensation expense associated with grants of restricted stock and stock options to employees and consultants 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.

Stock-based compensation expense related to employee stock options is measured using the fair value of the underlying award at the grant date and is adjusted annually to reflect actual forfeitures. The Company recognizes

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

2. Summary of Significant Accounting Policies (Continued)

the actual forfeitures by reducing the employee stock-based compensation expense in the same period as the forfeitures occur. Stock-based compensation expense is then recognized on a straight-line basis over the vesting period, which is also the requisite service period.

The Company estimates the grant date fair value of each stock option grant using the Black-Scholes option pricing model. The use of the Black-Scholes option pricing model requires the Company to make assumptions with respect to the fair value of the common stock at the date of grant, the expected term of the stock option, the expected volatility of the Company's common stock consistent with the expected term of the stock option, the risk-free interest rate consistent with the expected term of the stock option and the expected dividend yield of the Company's common stock.

In estimating its stock price, the Company utilized a hybrid method consisting of an option-pricing method and a zero-value scenario. The Company lacks a sufficient history of company-specific historical and implied volatility information for its common stock. Therefore, it estimates its expected share price volatility based on the historical volatility of publicly traded peer companies. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. 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 stock option. Expected dividend yield is based on the fact that 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 and Unaudited Pro Forma Loss per Share

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the reporting period, without consideration for potentially dilutive securities. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares and potentially dilutive securities outstanding during the period determined using the treasury-stock and if-converted methods. For purposes of the diluted net loss per share attributable to common stockholders calculation, preferred stock, restricted stock and stock options considered to be potentially dilutive securities were excluded from the calculation of diluted net loss per share attributable to common

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

2. Summary of Significant Accounting Policies (Continued)

stockholders because their effect would be anti-dilutive and therefore, basic and diluted net loss per share attributable to common stockholders were the same for all reporting periods presented.

The unaudited pro forma basic and diluted weighted-average common shares outstanding used in the calculation of unaudited pro forma basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2019 has been prepared to give effect, upon a qualified initial public offering, to the automatic conversion of all outstanding shares of preferred stock into common stock as if the proposed initial public offering had occurred on January 1, 2019, or the date of issuance, if later.

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, which was organized as a limited liability company, operated under the default classification as a partnership until September 17, 2018. On September 17, 2018, the Company converted from a Delaware LLC to a Delaware corporation and changed its name to ViraCyte, Inc. The Company calculated an income tax expense for the remainder of the year. Prior to September 17, 2018, income tax expense or benefits were calculated at the members' level.

For the period subsequent to September 17, 2018, deferred income taxes are provided on the current year net operating loss and the future income tax considerations associated with temporary differences between carrying amounts of assets and liabilities for tax and financial reporting purposes.

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

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that subject the Company to credit risk consist primarily of cash, cash equivalents, restricted cash and short-term investments. Periodically, the Company maintains deposits in accredited financial

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

2. Summary of Significant Accounting Policies (Continued)

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, 2019 and 2018, 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 an unrealized gain from short-term investments during the year ended December 31, 2019, which met the criteria as other comprehensive income and, therefore, the Company’s comprehensive loss includes unrealized gains on those available-for-sale securities. For the year ended December 31, 2018 the Company’s comprehensive loss was equal to net loss.

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 feature 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

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

2. Summary of Significant Accounting Policies (Continued)

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.

For all asset classes of its leases, other than those relating to its contract manufacturing space, the Company has elected to account for the lease and non-lease components together for existing classes of underlying assets.

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 Adopted Accounting Pronouncements

In February 2016, the FASB issued Accounting Standard Update ("ASU") 2016-02, Leases (ASC 842), which requires an entity to recognize lease assets and lease liabilities on the balance sheet and to disclose key information about leasing arrangements. The Company elected the package of three practical expedients whereby the Company did not need to (1) reassess whether expired or existing contracts are or contain leases, (2) reassess the lease classification for any expired or existing leases or (3) reassess any initial direct costs for existing leases. Upon adoption, ASC 842 had no impact on the consolidated financial statements as the Company only had short-term leases (leases with terms of less than 12 months) at the time. Please refer to Note 5 for more information regarding the Company's adoption of new lease standard.

In June 2018, the FASB issued ASU 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 awards. The Company adopted ASU 2018-07 on January 1, 2019. After adoption of ASU 2018-07, the measurement date for non-employee awards is the date of the grant. The compensation expense for non-employees is recognized, without changes in the fair value of the award, over the requisite service period, which is the vesting period of the respective award. There was no material impact as a result of adopting this new standard.

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

2. Summary of Significant Accounting Policies (Continued)

In August 2018, the FASB issued ASU 2018-13 – *Fair Value Measurements (Topic 820): Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurements* (“ASU 2018-13”). The new standard removes certain disclosures, modifies certain disclosures and adds additional disclosures related to fair value measurement. The Company adopted ASU 2018-13 on January 1, 2019. There was no material impact as a result of adopting this new standard.

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 1, 2020 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:

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

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, 2019, all investments had contractual maturities within one year. The Company had no investments At December 31, 2018.

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

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, 2019			Total
	Level 1	Level 2	Level 3	
Cash equivalents:				
Money market fund	\$46,407	\$ —	\$ —	\$46,407
Demand deposit	10,027	—	—	10,027
Totals	<u>\$56,434</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$56,434</u>
Short-term investments:				
U.S. government treasury securities	\$64,993	\$ —	\$ —	\$64,993
Totals	<u>\$64,993</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$64,993</u>

(in thousands)	December 31, 2018			Total
	Level 1	Level 2	Level 3	
Restricted Cash:				
Certificates of deposit	\$1,610	\$ —	\$ —	\$1,610
Totals	<u>\$1,610</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$1,610</u>

During the years ended December 31, 2019 and 2018, there were no transfers between levels. The fair values of the Company's cash equivalents, consisting of a money market fund and demand deposit, are based on quoted market prices in active markets with no valuation adjustment.

The Company uses the carrying amounts of its restricted cash, unbilled grants receivable, subscriptions receivable, prepaid expenses and other current assets, accounts payable and accrued expenses to approximate their fair value due to the short-term nature of these amounts.

5. Leases

The Company leases an office space in Houston, Texas under an operating lease that expires in April 2020. 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 approximately \$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. In exchange for this dedicated manufacturing suite, AlloVir will pay the supplier a monthly fixed suite reservation fee that covers costs associated with reserving capacity for AlloVir as well as cleaning services, utilities, handling and maintenance of the manufacturing suite. The use of the dedicated manufacturing suite qualifies as an operating lease under ASC 842, as it includes an identified asset for the exclusive use by the Company at its direction.

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

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

5. Leases (Continued)

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, 2019 are as follows (in thousands):

2020	\$ 3,600
2021	3,600
2022	3,600
2023	2,100
Total lease payments	12,900
Less: interest (4.53% - 5.75%)	(1,141)
Total lease liability	<u>\$11,759</u>
Lease liability – current	\$ 3,067
Lease liability – long-term	\$ 8,692

Total rent expense was \$2.1 million and \$0.1 million for the years ended December 31, 2019 and 2018, respectively. Cash paid for operating leases was \$1.4 million for the year ended December 31, 2019. The weighted average remaining lease term is 3.5 years at December 31, 2019. The weighted average discount rate is 5.14%.

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

6. Property and Equipment, Net

Property and equipment, net consisted of the following:

(in thousands)	December 31, 2019
Equipment	\$ 339
Construction-in-progress	30
Total property and equipment	369
Less: accumulated depreciation	(19)
Property and equipment, net	<u>\$ 350</u>

Depreciation expense was approximately \$19,000 for the year ended December 31, 2019. The Company did not have any property and equipment at December 31, 2018.

7. Accrued Expenses

Accrued expenses consisted of the following:

(in thousands)	December 31,	
	2019	2018
Employee compensation and benefits	\$1,520	\$ —
Professional fees	445	356
Research and development	3,051	306
Other	147	12
Total accrued expenses	<u>\$5,163</u>	<u>\$674</u>

8. Sponsored Research and License Agreements***Baylor College of Medicine***

In December 2014, the Company entered into a sponsored research agreement (“SRA-1”) with Baylor College of Medicine (“BCM”), under which the Company agreed to pay BCM for performing certain research activities related to virus specific T-cell manufacturing. SRA-1 was amended in 2017 to extend the agreement and include new deliverables where upon signing in August 2017, a payment was made to BCM for \$0.1 million. In June 2018, SRA-1 was cancelled and a final payment of \$0.1 million was made in December 2018.

In June 2019, the Company entered into another 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 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 (which includes the technology developed under SRA-1) and related patent rights. Under the License Agreement, the Company agrees to use commercially reasonable efforts to develop and commercialize the licensed products

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

8. Sponsored Research and License Agreements (Continued)

in the United States, Germany, Italy, France, Spain, the United Kingdom and Japan. The license expires on a country-by-country basis, on the later of (i) the date of expiration of the last valid claim of the patent rights to expire in such country or (ii) the first date following the tenth anniversary of the first commercial sale of such Licensed Product (defined as any product, process or service that incorporates, utilizes or is made with the use of the Subject Technology or Patent Rights) in such country. After such expiration, the Company will have a perpetual, paid-in-full license in such country.

In May 2020, the Company amended the License Agreement (the “License Agreement Amendment”), 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 License Agreement Amendment 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 License Agreement Amendment in its entirety at any time for convenience upon a certain number of days’ written notice. BCM may terminate the License Agreement Amendment 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 License Agreement Amendment, 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 License Agreement Amendment, 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 License Agreement Amendment, 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 License Agreement Amendment, BCM would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits.

Collectively under the agreements above and for services provided by BCM the Company paid \$0.9 million and \$0.6 million during the years ended December 31, 2019 and 2018, respectively, and the payments were classified in research and development expense in the consolidated statements of operations and comprehensive loss.

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

8. Sponsored Research and License Agreements (Continued)

Primarily all costs incurred related to services provided by BCM under License agreements and SRA-1 discussed above qualify for reimbursement under one of the Company’s grants 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 from 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 is three years beginning September 1, 2017 through August 31, 2020. This grant has a matching requirement where the Company is obligated to match 50% of the grant funds used on the project. In addition, the grant includes other compliance requirements including the obligation for the Company to operate with a principal place of business in Texas.

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 for the treatment of BKV-associated Hemorrhagic Cystitis 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. The royalty obligation is subject to reduction if the Company pays royalties to other parties but in no event shall the royalties be less than 50% of payments that would normally be due under the agreement. After 400% of the grant award proceeds has been paid, the Company will pay CPRIT a royalty of 0.5% 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. No royalty payments were made under this license agreement in the years ended December 31, 2019 and 2018.

As discussed in Note 2, 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. Under this grant, the Company received \$4.0 million during the year ended December 31, 2018. The unexpended funds received under this grant are classified as restricted cash on the consolidated balance sheet totaling \$2.7 million at December 31, 2018. The Company recognized revenue of \$0.2 million and \$1.1 million for the years ended December 31, 2019 and 2018, respectively, for work performed and expenses incurred under the CPRIT Grant. At December 31, 2018, the Company had deferred revenue of \$2.7 million. 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. Notwithstanding the Company’s termination of the grant, the Company’s obligation to pay royalties to CPRIT will persist as described above.

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)	\$ —

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

9. Revenue (Continued)

The following table presents the changes in the Company's contract liabilities during the year ended December 31, 2018:

(in thousands)	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract liabilities:				
Deferred revenue	\$ —	\$ 3,983	\$ (1,320)	\$ 2,663

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. There was no contract liability at the beginning of the year ended December 31, 2018.

There were no costs incurred to obtain or fulfill the contract.

10. Funding Arrangements**GRANTS – NIH & SBIR**

In August 2016, the Company was awarded a \$0.8 million grant from the National Institute of Health (“NIH”) for the Phase II study of Viraly-m-A for the treatment of Adenovirus disease. The grant period was for three years beginning September 1, 2016 through August 31, 2019. The grant was cancelled in June 2018 with approximately \$0.3 million expended out of the total grant, with the remaining amount returned to the NIH. Under this grant, the Company received \$0.1 million during the year ended December 31, 2018.

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 31, 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 \$1.0 million and \$0.9 million during the years ended December 31, 2019 and 2018, respectively. The Company recognized income of \$0.9 million and \$1.0 million on incurred expenses during the years ended December 31, 2019 and 2018, respectively.

The NIH and SBIR grants do 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 these grants is recognized in other income, net in the consolidated statements of operations and comprehensive loss.

11. Members' Equity and LLC Conversion*Amended and Restated Limited Liability Company Agreement*

Prior to the LLC Conversion, the Company was funded by capital contributions from members, and the Company's operations were governed by its LLC Agreement, which was amended and restated several times through August 2018. The LLC Agreement provided the Managing Member with the power and discretion to manage and control the business and affairs of the Company. Under the LLC Agreement, the Company granted membership interest to Class A members through Class D members, each holding a membership percentage interest with only the Class A members having the right to vote. The LLC Agreement also set forth the rights of and restrictions on class members, including certain exercise options and other required actions. The LLC Agreement detailed the priority of distributions and application of the membership interests of each member upon the occurrence of a triggering event.

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

11. Members' Equity and LLC Conversion (Continued)

The Company awarded profits interests to consultants under an LLC incentive plan, all of which had a distribution threshold of \$10.0 million, representing the price above which profits interests would participate in distributions. Holders of profits interests would have been entitled to receive profits when and if distributions were in excess of the distribution threshold of the award set by the Managing Member on the date of grant.

The rights and preferences for Class A, Class B, Class C, Class D membership interests (the "Membership Interests") and profits interests holders, based upon the terms of the LLC Agreement, are summarized below, in order of liquidation preference:

- Class C members, which at the time of the LLC Conversion consisted solely of the former Managing Member of the LLC, were first in terms of priority of distributions in the normal course of business and upon the occurrence of a deemed liquidation event. Class C was entitled to a return of its contributed capital until reduced to zero. The rights and preferences of the Class C interests were determined to be akin to preferred stock.

- Class A members, which at the time of the LLC Conversion consisted solely of the former Managing Member of the LLC, were second in terms of priority of distributions in the normal course of business and upon the occurrence of a deemed liquidation event. Class A was entitled to a return of its contributed capital and interest on such contributed capital in the amount of 8% per annum, until reduced to zero. In addition, the Managing Member of the LLC, through the Class A membership interests, held 100% of the voting rights over the LLC. The rights and preferences of the Class A interests were determined to be akin to preferred stock.

- Class D members, which at the time of the LLC Conversion were comprised of consultants, former consultants and third party investors, were third in terms of priority of distributions in the normal course of business and upon the occurrence of a deemed liquidation event. Class D was entitled to a return of its contributed capital until reduced to zero. The rights and preferences of the Class D interests were determined to be akin to preferred stock.

- Class B members and profits interests holders, which at the time of the LLC Conversion were comprised of consultants and former consultants, shared pro-rata in any remaining residual distributions with all the other holders, in the normal course of business and upon the occurrence of a deemed liquidation event (with the profits interests holders being further subject to the distribution threshold being met before participating in distributions). The rights and preferences of the Class B interests and profits interests were determined to be akin to common stock.

The following table is a summary of each class member's capital contributions, including interest accrued, and membership percentage interest held immediately before the LLC Conversion and execution of Series A2 Preferred Stock Agreement:

(in thousands)	September 17, 2018	
	<u>Amount</u>	<u>Ownership Percentage</u>
Class A Membership Interest	\$ —	23.1%
Class B Membership Interest	—	41.9%
Class C Membership Interest	2,264	13.6%
Class D Membership Interest	1,321	7.4%
Profits Interests	144	14.0%
	<u>\$3,729</u>	<u>100.0%</u>

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

11. Members' Equity and LLC Conversion (Continued)

Upon the consummation of the LLC Conversion, the Company converted into a corporation, and the LLC Agreement no longer governs the Company's operations or the rights of its equity holders. See additional discussion related to the accounting for the LLC Conversion in Note 12.

12. Convertible Preferred Stock and Stockholders' Deficit**Common Stock**

Upon consummation of the LLC Conversion, the Company issued one share of common stock to the Managing Member of the LLC. The voting, dividend and liquidation rights of the holders of the Company's common stock is subject to and qualified by the rights, powers and preferences of the holders of the preferred stock as set forth below.

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 Certificate of Incorporation.

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

	December 31, 2019
Preferred stock, as converted	39,859,139
Unvested restricted stock units and stock options outstanding under the 2018 Equity Incentive Plan	4,448,133
Stock available for grant under the 2018 Equity Incentive Plan	486,082
	<u>44,793,354</u>

The Company had authorized 7,033,971 shares of common stock available for grant under the Company's 2018 Equity Incentive Plan (see Note 13). The summary of plan activity for shares issued and outstanding and the number of shares remaining available for grant under the plan are as follows:

	December 31, 2019
Common stock granted under the 2018 Equity Incentive Plan	6,547,889
Common stock available for grant under the 2018 Equity Incentive Plan	486,082
	<u>7,033,971</u>

As of December 31, 2019, there were 2,099,740 shares of common stock that were vested of the 6,547,889 shares of common stock granted under the 2018 Equity Incentive Plan.

Convertible Preferred Stock

In conjunction with the LLC Conversion on September 17, 2018, the Company (i) simultaneously issued Series A1 Preferred Stock, and (ii) entered into a Redeemable Preferred Stock Redemption Agreement (the "Redemption Agreement") with the former members of the LLC, and executed the Series A2 Agreement, issuing 20,000,000 shares of Series A2 Preferred Stock to a new investor.

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

12. Convertible Preferred Stock and Stockholders' Deficit (Continued)

Series A1 Preferred Stock Conversion and Redeemable Convertible Preferred Stock (Redemption Agreement)

As a result of the LLC Conversion and in accordance with the Agreement and Plan of Conversion between ViraCyte LLC and its members, the Company issued 26,666,666 shares of Series A1 Preferred Stock, of which 6,666,666 was designated as Redeemable Preferred Stock, with each member of the LLC receiving a pro-rata portion of the Series A1 Preferred Stock in accordance with their membership interest percentage. The Redeemable Preferred Stock was distributed to LLC members other than holders of profits interests, and this issuance to LLC members was deemed to satisfy the distribution threshold of the profits interests.

In accordance with the Redemption Agreement and contemporaneous with the LLC Conversion, the Redeemable Preferred Stock was simultaneously redeemed for an aggregate purchase price of \$10.0 million, plus an earnout payment. As the Redemption Agreement was issued in the form of shares and embodied an unconditional obligation requiring the Company to redeem the Redeemable Preferred Stock by transferring its assets at a specified or determinable date, the Redeemable Preferred Stock met the definition of a mandatorily redeemable financial instrument and was required to be classified as a liability upon issuance. The earnout payment is equal to 10% multiplied by the Company's net sales of Viralym-M, less the Company's then existing third party obligations from the sale of Viralym-M Product. The earnout percentage will be reduced to a high single-digit percentage under certain conditions. These earnout payments will be for a period of 20 years from the date of the first commercial sale of Viralym-M Product by the Company. The earnout represents a contingent payment that the Company concluded had *de minimis* value at the date of the Redemption Agreement or at December 31, 2019 or 2018.

With the exception of the third-party investors who held a portion of the Class D membership interests, the remaining membership interests (and profits interests) were held by nonemployee service providers. For the nonemployee service providers, the exchange of membership interests for Series A1 Preferred Stock and Redeemable Preferred Stock described above was evaluated to determine whether any incremental fair value was transferred to these nonemployee service providers as a result of these transactions. Accordingly, the Company performed a fair value analysis for each nonemployee service provider which compared the fair value of the previously outstanding membership interests and profits interests held immediately prior to the LLC Conversion with the fair value of the Series A1 Preferred Stock and Redeemable Preferred Stock held immediately after the LLC Conversion. Based upon this analysis, the Company determined there was an increase in fair value attributed primarily to holders of Class A and Class C membership interest, which resulted in the recognition of \$0.1 million of stock-based compensation expense at the time of the LLC Conversion.

Additionally, as previously noted, the Class A, C and D membership interests were determined to be akin to preferred stock whereas the Class B membership interests and profits interests were determined to be akin to common stock. Therefore, the exchange of the Class A, C and D membership interests for the Redeemable Preferred Stock and Series A1 Preferred Stock represented both (i) a partial extinguishment for those membership interests exchanged for the Redeemable Preferred Stock, which was immediately settled in cash and (ii) a modification of the remaining membership interests exchanged for the Series A1 Preferred Stock. For the partial extinguishment, the Company recognized a deemed dividend of \$5.7 million for the difference between (i) the fair value of the respective Redeemable Preferred Stock and (ii) the carrying value of the related Class A, C and D membership interests at the time of the extinguishment. For the Class B membership interests, the exchange of the Redeemable Preferred Stock was treated as a repurchase of common stock at fair value and the difference between the fair value of the Redeemable Preferred Stock and the carrying value of the respective Class B membership interests was recognized as a reduction to equity. The exchange of the Class B membership interests and profits interests for the Series A1 Preferred Stock represented an extinguishment of Class B membership interests and profits interests as the exchange was an exchange of equity akin to common stock for

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

12. Convertible Preferred Stock and Stockholders' Deficit (Continued)

preferred stock, and the Series A1 Preferred Stock received by the former Class B members and profits interests was recorded at fair value, in the amount of \$16.8 million.

For the remaining membership interests exchanged for Series A1 Preferred Stock that represented a modification, the Company did not recognize any increase in fair value as the fair value of the membership interests held immediately before the LLC Conversion and the fair value of the Series A1 Preferred Stock held immediately after the LLC Conversion was similar.

Series A2 Preferred Stock

On September 17, 2018, the Board of Directors authorized the sale and issuance of 20,000,000 shares of Series A2 Preferred Stock at a purchase price \$1.50 per share to ElevateBio. The Company received cash proceeds of \$29.8 million, net of \$0.2 million of issuance costs.

Series A3 Preferred Stock

On May 8, 2019, in the connection with closing of the Series B Preferred Stock transaction noted below and in accordance with the anti-dilution rights held by the holders of Series A1 Preferred Stock, the Company converted all Series A1 Preferred Stock held to Series A3 Preferred Stock on a one for one basis, as well as issued an additional 2,453,987 shares of Series A3 Preferred Stock to those holders.

Series A4 Preferred Stock

On December 12, 2018, the Board of Directors authorized the sale and issuance of 2,066,666 shares of Series A4 Preferred Stock at a purchase price \$1.50 per share for a total purchase price of \$3.1 million. At December 31, 2018, the Company received cash proceeds of \$3.0 million and recorded a subscription receivable for the remaining \$0.1 million that was paid on January 18 and 22, 2019. The holders of Series A4 Preferred Stock have all the same rights as Series A1, A2, and A3, except they are non-voting.

Series B Preferred Stock

On May 8, 2019, the Company completed a financing, issuing 14,877,697 shares of Series B Preferred Stock at a purchase price of \$8.15 per share for a total proceeds of \$120.9 million, net of issuance costs of \$0.3 million. The holders of Series B Preferred Stock have substantially the same rights and privileges as the holders of Series A2 Preferred Stock and Series A3 Preferred Stock.

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

(in thousands, except share amounts)	December 31, 2019				Common Stock Issuable Upon Conversion
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	
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	14,877,697	14,877,697	120,923	121,253	9,983,632
Total	<u>79,398,350</u>	<u>59,398,350</u>	<u>\$ 173,127</u>	<u>\$ 188,034</u>	<u>39,859,139</u>

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

12. Convertible Preferred Stock and Stockholders' Deficit (Continued)

At December 31, 2018, preferred stock consisted of the following:

(in thousands, except share amounts)	December 31, 2018				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
Series A1 Preferred Stock	20,000,000	20,000,000	\$ 19,364	\$ 30,000	13,420,970
Series A2 Preferred Stock	33,333,334	20,000,000	29,775	30,000	13,420,970
Series A3 Preferred Stock	33,333,334	—	—	—	—
Series A4 Preferred Stock	2,066,666	2,066,666	3,065	3,100	1,386,831
Total	<u>88,733,334</u>	<u>42,066,666</u>	<u>\$ 52,204</u>	<u>\$ 63,100</u>	<u>28,228,771</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, have the following rights and preferences:

Voting

The holders of preferred stock are 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 be converted. The holders of a majority of the then outstanding preferred stock shall have 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, require the affirmative vote of the holders of preferred stock, voting separately as a single class. These matters include 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 require 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 is convertible into common stock at any time after the date of issuance. The initial conversion price is equal to the original issue price per share (\$1.50 for Series A Preferred Stock and \$8.15 for Series B Preferred Stock) and is subject to adjustment as disclosed in Certificate of Incorporation. Each preferred stock will automatically convert into common stock at an 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.

As of December 31, 2019, the applicable conversion price of the Preferred Stock is \$2.24 for the Series A Preferred Stock and \$12.15 for the Series B Preferred Stock.

Dividends

The holders of preferred stock are 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.

Liquidation Preference

In the event of a liquidation of the Company, the holders of Series B Preferred Stock shall be paid, in preference to Series A Preferred Stock and common stock, the greater of 1) the Series B Preferred Stock original

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

12. Convertible Preferred Stock and Stockholders' Deficit (Continued)

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 are insufficient to pay the Series B Preferred Stock, the holders of Series B Preferred Stock will 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 shall 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 are insufficient to pay the Series A Preferred Stock, the holders of Series A Preferred Stock will share ratably in the distribution of the assets based on the distribution that would have otherwise been paid in full.

Redemption

The Company has determined that all series of preferred stock are redeemable, based on the Certificate of Incorporation that states upon the occurrence of a deemed liquidation event, the holders of preferred stock are 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 is required to issue additional preferred stock and ElevateBio is 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 represents 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 contain 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 at December 31, 2019 and 2018, the Company concluded that the fair value was *de minimis* based on the probabilities of such events occurring at such dates. The Company will reassess the fair value of such embedded derivative each reporting period and any changes in fair value will be recorded in the consolidated statements of operations and comprehensive loss.

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

13. Stock-Based Compensation

Profits Interests

On September 17, 2018, all vested profits interests were converted into 2,800,000 shares of Series A1 Preferred Stock, in accordance with the LLC Conversion discussed in Note 11. There were no grants or vests of profits interests during the year ended December 31, 2018.

2018 Equity Incentive Plan

On September 17, 2018, the Board of Directors and stockholders approved the 2018 Equity Incentive Plan. The 2018 Equity Incentive Plan allows for the issuance of up to 7,033,971 incentive or non-qualified stock options, restricted stock or restricted stock units, or unrestricted stock to employees, consultants or advisors of the Company which vest in accordance with the specific terms of each individual grant (generally over four-year periods). The number of stock options, restricted stock, or restricted stock units and unrestricted stock is subject to adjustment as a result of a reorganization, recapitalization, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock. At December 31, 2019, the Company had 4,448,133 shares of unvested restricted stock units and stock options outstanding and 486,082 shares available for grant under the 2018 Equity Incentive Plan.

Restricted Stock

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

The Company granted 4,118,077 shares of restricted stock to employees in 2018, of which 747,231 shares vested immediately. Stock-based compensation expense recognized for the restricted stock granted was \$0.9 million for the year ended December 31, 2018.

All unvested restricted stock (other than those becoming vested as a result of the Sale Event) issued shall be forfeited immediately prior to the effective time of any such Sale Event unless assumed or continued by the successor entity, or awards of the successor entity or parent thereof are substituted therefor. A Sale Event means the consummation of (i) the dissolution or liquidation of the Company, (ii) the sale of all or substantially all of the assets of the Company on a consolidated basis to an unrelated person or entity, (iii) a merger, reorganization or consolidation pursuant to which the holders of the Company's outstanding voting power immediately prior to such transaction do not own a majority of the outstanding voting power of the surviving or resulting entity (or its ultimate parent, if applicable), (iv) the acquisition of all or a majority of the outstanding voting stock of the Company in a single transaction or a series of related transactions by a person or group of persons, or (v) any other acquisition of the business of the Company.

Also, in the event of a Sale Event, the Company shall have the right, but not the obligation, to make or provide for a cash payment to the holders of restricted stock, without any consent of the holders, in exchange for the cancellation thereof, in an amount equal to the difference between (A) the value as determined by the board of directors of the consideration payable per share of stock pursuant to the Sale Event (the "Sale Price") times the number of shares subject to outstanding restricted stock being cancelled (to the extent then vested and exercisable, including by reason of acceleration in connection with such Sale Event, at prices not in excess of the Sale Price) and (B) the aggregate exercise price of all such outstanding vested and exercisable restricted stock.

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

13. Stock-Based Compensation (Continued)

The following table summarizes restricted stock activity for the year ended December 31, 2019:

	Shares	Weighted Average Grant Date Fair Value
Unvested at January 1, 2019	3,370,805	\$ 1.06
Granted	2,434,515	2.93
Forfeited	(49,827)	1.06
Vested	(1,352,345)	1.80
Unvested at December 31, 2019	<u>4,403,148</u>	<u>\$ 1.87</u>

The weighted average grant-date fair value of restricted stock granted in 2018 was \$1.06 per share. At December 31, 2019, there was approximately \$7.7 million of unrecognized stock-based compensation cost related to the restricted stock, which is expected to be recognized over a weighted average period of 3.2 years.

Non-Qualified Stock Options

In October 2019, the Company granted 44,960 non-qualified stock options to a consultant, none of which vested in 2019. They vest over a four-year period and have a 10-year contractual term. There were no stock options granted in 2018. The following table summarizes stock option activity for the year ended December 31, 2019:

	Shares	Weighted Average Exercise Price	Weighted Average Contractual Life	Aggregate Intrinsic Value
Options outstanding at January 1, 2019	—	\$ —		
Granted	44,960	3.01		
Forfeited	—	—		
Exercised	—	—		
Options outstanding at December 31, 2019	44,960	\$ 3.01	9.8	\$ —
Options exercisable at December 31, 2019	—	\$ —	—	\$ —
Options unvested and expected to vest at December 31, 2019	44,960	\$ 3.01	9.8	\$ —

The weighted average grant-date fair value of stock options granted in 2019 was \$2.17 per share. At December 31, 2019, there was approximately \$0.1 million of unrecognized stock-based compensation cost related to the non-qualified stock options, which is expected to be recognized over 3.5 years. There were no stock options granted during the year ended December 31, 2018.

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

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

The Company adopted ASU 2018-07 as of January 1, 2019; accordingly, the assumptions used during the year ended December 31, 2019 shall be applied to both employee and non-employee awards. During the year

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

13. Stock-Based Compensation (Continued)

ended December 31, 2018 the Company had not yet adopted ASU 2018-07. All awards granted prior to January 1, 2019 were to non-employees.

Stock-Based Compensation Expense

Stock-based compensation expense was as follows:

(in thousands)	Year Ended December 31,	
	2019	2018
Research and development	\$ 547	\$ 15
General and administrative	2,343	843
Total stock-based compensation expense	\$2,890	\$858

An additional \$0.1 million of stock-based compensation expense was recorded during the year ended December 31, 2018 as a result of the LLC Conversion. See Note 12.

14. Income Taxes

The Company, which was organized as a limited liability company, operated under the default classification as a partnership until September 17, 2018. On September 17, 2018, the Company converted from a Delaware LLC to a Delaware corporation and, as such, became subject to income tax and a net deferred tax asset was created. The Company calculated an income tax expense for the remainder of the year. The Company's income tax expense (benefit) for the year ended December 31, 2019 and the period from September 17, 2018 through December 31, 2018 relating to federal and state tax jurisdictions differs from the amounts determined by applying the statutory federal income tax rate based on the following:

Reconciliation between the statutory effective tax rate and the tax rate on income is as follows (in thousands):	For the year ended December 31, 2019		For the period from September 17, 2018 through December 31, 2018	
Benefit at the federal rate	\$ (5,006)	21.0%	\$ (378)	21.0%
Increase (decrease) resulting from:				
State taxes, net of federal benefit	(565)	2.4%	—	0.0%
Non-deductible expenses	6	(0.0%)	—	(0.0%)
Change in valuation allowance	6,354	(26.7%)	445	(24.7%)
R&D tax credits	(753)	3.2%	—	—
Other	(36)	0.1%	—	(0.0%)
Opening deferred balance	—	—	(67)	3.7%
Total Income Tax Expense/(Benefit)	\$ —	—	\$ —	—

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

14. Income Taxes (Continued)

Components of deferred income taxes consist of (in thousands):	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	\$ 7,604	\$ 427
Operating lease liabilities	2,747	—
Deferred revenue	—	555
R&D tax credits	753	—
Other	183	87
Total deferred tax assets	<u>11,287</u>	<u>1,069</u>
Deferred tax liabilities:		
Operating lease right-of-use assets	(2,747)	—
Restricted stock compensation	(1,650)	(624)
Depreciation	(75)	—
Other	(16)	—
Total deferred tax liabilities	<u>(4,488)</u>	<u>(624)</u>
Valuation allowance	(6,799)	(445)
Net deferred tax asset (liability)	<u>\$ —</u>	<u>\$ —</u>

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 present, 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 period from September 17, 2018 through December 31, 2018, the valuation allowance for deferred tax assets increased by \$0.4 million, which was due principally to a current year net operating loss and deferred revenue. For the year ended December 31, 2019, the valuation allowance for deferred tax assets increased by \$6.4 million, which was principally due to the net operating loss.

At December 31, 2019, the Company had unused federal and state net operating loss carryforwards of approximately \$32.8 million and \$11.4 million, respectively. The federal net operating loss carryforwards have no expiration. The state net operating loss carryforwards expire in 2039. At December 31, 2019, the Company had \$0.6 million of research and development tax credit carryforwards that may be available to offset future federal income taxes through 2039. The Company also had \$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 2034.

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

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

14. Income Taxes (Continued)

be recorded in the consolidated financial statements. Under ASC 740, the Company may recognize the tax benefit from an uncertain tax position only if it is more likely that not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. At December 31, 2019 and 2018, the Company had no uncertain tax positions.

The Company recognizes interest accrued related to unrecognized tax benefits and penalties in income tax expense. The Company had no accruals for interest and penalties at December 31, 2019 and 2018.

The Company is required to file income tax returns in the U.S. Federal jurisdiction, and in the States of Massachusetts and Texas. The statute of limitations for assessment by the Internal Revenue Service and state tax authorities remains open for tax years ending after December 31, 2015. There are currently no federal or state income tax audits in progress.

15. Net Loss per Share and Unaudited Pro Forma 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)	Year Ended December 31, 2019	For the period from September 17, 2018 through December 31, 2018 (1)
Numerator:		
Net loss attributable to common stockholders	\$ (23,839)	\$ (1,911)
Loss on deemed dividend (Note 12)	—	(5,726)
Net loss attributable to common stockholders – basic and diluted	<u>\$ (23,839)</u>	<u>\$ (7,637)</u>
Denominator:		
Weighted-average common shares outstanding – basic and diluted	1,285,933	204,431
Net loss per share attributable to common stockholders – basic and diluted	<u>\$ (18.54)</u>	<u>\$ (37.36)</u>

- (1) Prior to the LLC Conversion on September 17, 2018, the Company was funded by capital contributions in exchange for Class A through Class D membership interests, with each member holding a percentage interest in the Company with only the Class A members having the right to vote. Additionally, the Company awarded profits interests to consultants who were entitled to receive profits when and if distributions exceeded the distribution threshold set by the Managing Member. The rights and preferences of the Class A, Class C and Class D members were determined to be akin to participating preferred stock with no contractual obligation to share in net losses, and the rights and preferences of the Class B members and profits interests holders were determined to be akin to common stock. Refer to Note 11 for details. No units or shares of the Company were issued while the Company was an LLC.

On September 17, 2018, in connection with the LLC Conversion, the Company issued one share of common stock to the Managing Member of the LLC and issued shares of Series A1 Preferred Stock, with each member of the LLC receiving shares of stock in accordance with their membership interest percentage. For clarity, Class A through Class D members and holders of profits interests did not hold units of each respective class of interest prior to the LLC Conversion, rather, each held a membership interest percentage in the Company immediately prior to the LLC Conversion (refer to Note 11 for membership interest percentages). Accordingly, basic and diluted loss per share is presented for the period from September 17, 2018 through December 31,

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

15. Net Loss per Share and Unaudited Pro Forma Net Loss Per Share (Continued)

2018 (subsequent to the LLC Conversion), the period during which common stock was outstanding during the year ended December 31, 2018. Had the Company issued units or shares of the Company to the Class A through Class D members and profits interests holders prior to the LLC Conversion, basic and diluted loss per share would have been presented for the full year ended December 31, 2018 using the units or shares issued to the Class B members and profits interests holders, in addition to common stock issued in connection with and subsequent to the LLC Conversion, as the rights and preferences of the Class B members and profits interests holders were determined to be akin to common stock.

Loss per unit prior to the LLC Conversion defined and described in Note 11 to these consolidated financial statements is not presented, as there were no units outstanding prior to such and substantially different classes of units were issued as part of the LLC Conversion. The loss per unit for the period from September 17, 2018 through December 31, 2018 was calculated and presented prospectively from the date of issuance using net loss for that period only.

At December 31, 2019 and 2018, the Company's potentially dilutive securities were preferred stock, unvested restricted stock and stock options, which have been excluded from the computation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2019 and the period from September 17, 2018 to December 31, 2018, as the effect would be to reduce the net loss per share attributable to common stockholders. Based on the amounts outstanding at December 31, 2019 and 2018, the Company excluded the following potential common shares from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Year Ended December 31,	
	2019	2018
Series A1 Preferred Stock	—	13,420,970
Series A2 Preferred Stock	13,420,970	13,420,970
Series A3 Preferred Stock	15,067,706	—
Series A4 Preferred Stock	1,386,831	1,386,831
Series B Preferred Stock	9,983,632	—
Options to purchase common stock	44,960	—
Unvested restricted stock	4,403,148	3,370,805

Unaudited pro forma net loss per share attributable to common stockholders is computed using the weighted average number of common shares outstanding after giving effect to the conversion of all outstanding convertible preferred stock into common shares as if such conversion had occurred on January 1, 2019, or the date of issuance, if later.

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

15. Net Loss per Share and Unaudited Pro Forma Net Loss Per Share (Continued)

Unaudited pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

(in thousands, except share and per share data)	<u>Year Ended December 31, 2019</u>
Numerator:	
Net loss attributable to common stockholders	\$ (23,839)
Net loss attributable to common stockholders – basic and diluted	<u>\$ (23,839)</u>
Denominator:	
Weighted-average common shares outstanding – basic and diluted	1,285,933
Pro forma adjustment to reflect automatic conversion of convertible preferred stock to common stock upon the completion of the proposed initial public offering	<u>35,812,408</u>
Pro forma weighted-average common shares outstanding – basic and diluted	<u>37,098,341</u>
Pro forma net loss per share attributable to common stockholders – basic and diluted	<u>\$ (0.64)</u>

16. Commitments and Contingencies***Leases***

The Company leases an office space in Houston, Texas under an operating lease that expires in April 2020. The Company also sub-leases 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, 2019, there were no matters which would have a material impact on the Company's financial results.

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 or 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. The Company incurred \$3.2 million and \$0.2 million of expenses during the years ended

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

17. Related Party Transactions (Continued)

December 31, 2019 and 2018, respectively, related to services provided to the Company by ElevateBio and affiliates. At December 31, 2019 and 2018, the Company owes ElevateBio \$0.2 million, which is recorded in Amount due to related party on the consolidated balance sheets.

During the years ended December 31, 2019 and 2018, Wilson Wolf Manufacturing Corporation (“Wilson Wolf”) provided services to the Company in the amount of \$0.1 million and \$0.4 million, respectively. The former Managing Member of ViraCyte LLC and current board member of the Company is the founder and owner of Wilson Wolf. The expenses incurred in connection with the services are included as research and development expenses in the accompanying consolidated statements of operations and comprehensive loss.

During the years ended December 31, 2019 and 2018, members of the Company’s management received a total of \$0.4 million and \$0.9 million, respectively, in consulting fees.

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 which totaled \$0.1 million in 2019.

19. Subsequent Events

The Company has evaluated all subsequent events through June 3, 2020, the date the consolidated financial statements were available to be issued and through July 23, 2020, as it relates to the Reverse Stock Split. The following events occurred subsequent to December 31, 2019:

CARES Act

The United States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an approximately \$2 trillion emergency economic stimulus package in response to the Coronavirus outbreak, which among other things contains numerous income tax provisions. Some of these tax provisions are expected to be effective retroactively for years ending before the date of enactment. The Company is currently evaluating the impact of the CARES Act on its consolidated financial position, results of operations, and cash flows.

COVID-19 Pandemic Response and Impact

In March 2020, the World Health Organization declared the outbreak of novel coronavirus disease (“COVID-19”) as a pandemic. The Company expects its operations to be affected as the virus continues to proliferate. The Company has adjusted certain aspects of its operations to protect employees while avoiding business interruption. Only employees essential to the development and research of our product candidates remain on-site at our research and manufacturing facilities. The outbreak and any preventative or protective actions that the Company, its suppliers or other third parties with which the Company has business relationships, or governments may take in respect of the COVID-19 outbreak could disrupt the Company’s business operations. Global health concerns, such as COVID-19, could also result in social, economic and labor instability in the countries in which the Company or third parties with whom the Company engages operate. In addition, the COVID-19 outbreak could result in a severe economic downturn and has already significantly affected the financial markets of many countries. A severe or prolonged economic downturn or political disruption could

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

19. Subsequent Events (Continued)

result in a variety of risks to the Company, including the Company's ability to raise capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain suppliers or third party CMOs, possibly resulting in research and manufacturing disruptions or clinical trial delays for the Company's product candidates. The COVID-19 pandemic may also create delays in the review and approval of regulatory submissions of the Company's product candidates by the FDA.

The Company will continue to monitor the situation closely and react accordingly to any future restrictions or limitations while keeping the health of its employees and the interest of the business in mind. Due to the uncertainty in the severity and duration of the pandemic, the impact on our revenues, profitability and statement of financial position is uncertain at this time.

Amendments to Baylor Agreements

On March 23, 2020, the Company expanded its research and development collaboration with Baylor College of Medicine 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.

On May 12, 2020, the Company amended and restated the License Agreement with BCM (see Note 8), 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 additional technology developed by Baylor under SRA-2 since the original License Agreement was executed. Under the terms of the License Agreement Amendment, the license agreement amendment establishes royalties and milestones for the added pre-clinical products; on the SARS-CoV-2 product. Additionally, the Company is obligated to pay BCM \$3.0 million upon the Food and Drug Administration's approval of a licensed product for the prevention and treatment of COVID-19 as well as sales-based milestone payments of up to \$37.5 million from the commercial sale of such Licensed Product.

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.

ALLOVIR, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
UNAUDITED

(in thousands, except share and per share amounts)	Pro Forma March 31, 2020	March 31, 2020	December 31, 2019
Assets			
Current assets:			
Cash and cash equivalents	\$ 64,380	\$ 64,380	\$ 61,084
Short-term investments	51,354	51,354	64,993
Accrued interest	311	311	262
Unbilled grant receivables	346	346	298
Prepaid expenses and other current assets	960	960	676
Total current assets	117,351	117,351	127,313
Property and equipment	332	332	350
Operating lease right-of-use assets	11,007	11,007	11,759
Total assets	<u>\$128,690</u>	<u>\$128,690</u>	<u>\$ 139,422</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)			
Current liabilities:			
Accounts payable	\$ 1,812	\$ 1,812	\$ 630
Accrued expenses	2,276	2,276	5,163
Operating lease liability, current	3,107	3,107	3,067
Amount due to related party	488	488	246
Total current liabilities	7,683	7,683	9,106
Operating lease liability, long term	7,900	7,900	8,692
Total liabilities	<u>15,583</u>	<u>15,583</u>	<u>17,798</u>
Series B preferred stock, \$0.0001 par value: 14,877,697 shares authorized, issued and outstanding at March 31, 2020 and December 31, 2019; net of issuance costs (liquidation value of \$121.3 million); no shares authorized, issued or outstanding, pro forma as of March 31, 2020	—	120,923	120,923
Series A preferred stock, \$0.0001 par value: 64,520,653 shares authorized at March 31, 2020 and December 31, 2019; 44,520,653 shares issued and outstanding at March 31, 2020 and December 31, 2019; net of issuance costs (liquidation value of \$66.8 million); no shares authorized, issued or outstanding, pro forma as of March 31, 2020	—	52,204	52,204
Stockholders' equity (deficit):			
Common stock, \$0.0001 par value: 90,000,000 shares authorized at March 31, 2020 and December 31, 2019; 6,559,348 and 6,502,929 issued at March 31, 2020 and December 31, 2019, respectively; 2,392,397 and 2,099,740 outstanding at March 31, 2020 and December 31, 2019, respectively. 90,000,000 shares authorized and 42,251,536 shares issued and outstanding, pro forma as of March 31, 2020	6	—	—
Additional paid-in capital	177,515	4,394	3,748
Accumulated other comprehensive income	244	244	68
Accumulated deficit	(64,658)	(64,658)	(55,319)
Total stockholders' equity (deficit)	113,107	(60,020)	(51,503)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$128,690</u>	<u>\$128,690</u>	<u>\$ 139,422</u>

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

ALLOVIR, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
UNAUDITED

(in thousands, except share and per share amounts)	Three Months Ended March 31,	
	2020	2019
Revenue	\$ —	\$ 165
Operating expenses:		
Research and development	6,839	1,151
General and administrative	3,001	1,787
Total operating expenses	9,840	2,938
Loss from operations	(9,840)	(2,773)
Total other income, net:		
Interest income	457	116
Other income, net	44	133
Net loss and net loss attributable to common stockholders	\$ (9,339)	\$ (2,524)
Net loss per share attributable to common stockholders — basic and diluted	\$ (4.21)	\$ (3.19)
Weighted-average common shares outstanding — basic and diluted	2,215,958	792,376
Pro forma net loss per share attributable to common stockholders — basic and diluted	\$ (0.22)	
Pro forma weighted-average common shares outstanding - basic and diluted	42,075,097	
Comprehensive loss:		
Net loss	\$ (9,339)	\$ (2,524)
Other comprehensive income, net of tax:		
Unrealized gain on available-for-sale securities	176	—
Total other comprehensive income	176	—
Comprehensive loss	\$ (9,163)	\$ (2,524)

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

ALLOVIR, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND CHANGES IN STOCKHOLDERS' DEFICIT

UNAUDITED

(in thousands, except share amounts)	Series B Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	—	\$ —	42,066,666	\$52,204	747,231	\$ —	\$ 858	—	\$ (31,480)	\$ (30,622)
Issuance of common stock, upon vesting of restricted stock	—	—	—	—	140,106	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	231	—	—	231
Net loss	—	—	—	—	—	—	—	—	(2,524)	(2,524)
Balance at March 31, 2019	—	\$ —	42,066,666	\$52,204	887,337	\$ —	\$ 1,089	\$ —	\$ (34,004)	\$ (32,915)
(in thousands, except share amounts)	Series B Preferred Stock		Series A Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
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)
Issuance of common stock, upon vesting of restricted stock	—	—	—	—	292,644	—	—	—	—	—
Stock-based compensation	—	—	—	—	—	—	646	—	—	646
Unrealized gain on available-for-sale securities	—	—	—	—	—	—	—	176	—	176
Net loss	—	—	—	—	—	—	—	—	(9,339)	(9,339)
Balance at March 31, 2020	14,877,697	\$120,923	44,520,653	\$52,204	2,392,384	\$ —	\$ 4,394	\$ 244	\$ (64,658)	\$ (60,020)

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

ALLOVIR, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
UNAUDITED

(in thousands)	Three Months Ended March 31,	
	2020	2019
Cash flows from operating activities		
Net loss	\$ (9,339)	\$ (2,524)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	18	—
Accretion of discounts on short-term investments	(24)	—
Stock compensation expense	646	231
Changes in operating assets and liabilities:		
Unbilled grants receivable	(48)	(136)
Accrued interest	(49)	—
Prepaid expenses and other current assets	(284)	(226)
Accounts payable, accrued expenses and amount due to related party	(1,463)	836
Deferred grant revenue	—	(158)
Net cash used in operating activities	(10,543)	(1,977)
Cash flows from investing activities		
Purchase of property and equipment	—	—
Purchase of short-term investments	(21,161)	—
Maturities of short-term investments	35,000	—
Net cash provided by investing activities	13,839	—
Cash flows from financing activities		
Issuance costs related to the issuance of preferred stock	—	(31)
Net cash used in financing activities	—	(31)
Net increase (decrease) in cash and cash equivalents	3,296	(2,008)
Cash and cash equivalents at beginning of period	61,084	24,960
Cash and cash equivalents at end of period	\$ 64,380	\$22,952
Non-cash investing and financing activities		
Unrealized gain on short-term investments	176	—
Right-of-use assets obtained in exchange for operating lease liability	—	6,890

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

ALLOVIR, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
UNAUDITED

1. Nature of the Business

AlloVir, Inc., (“AlloVir” or “the Company”, formerly known as ViraCyte, Inc.) is a clinical-stage cell therapy company focused on developing allogeneic, off-the-shelf multi-virus specific T cell (“VST”) therapies to prevent and treat severe viral-associated diseases. AlloVir is built upon a technology platform to restore natural immune defenses in immunocompromised patients. AlloVir’s lead asset, Vivalym-M has completed a Phase 2 clinical trial for the treatment of cytomegalovirus (“CMV”), adenovirus (“AdV”), BK virus (“BKV”), human herpesvirus 6 (“HHV-6”), and Epstein-Barr virus (“EBV”) associated conditions in drug refractory patients post-allogeneic hematopoietic stem-cell transplant (“HSCT”).

The Company is planning to initiate numerous clinical trials in the 2nd half of 2020 to treat viral complications in both HSCT and solid organ transplant (“SOT”) immunocompromised patient populations. In HSCT, Phase 3 clinical trials will include the treatment of BKV-associated Hemorrhagic Cystitis AdV, and CMV; a Phase 2 multivirus (CMV, BKV, EBV, AdV and HHV-6 trial is being planned; and a SOT trial investigating Vivalym-M among patients with BK-nephropathy. Additionally, ALVR106 a second multi-virus specific T cell therapy targeting common respiratory viral pathogens (respiratory syncytial virus (“RSV”), influenza, human metapneumovirus (“hMPV”), and parainfluenza (“PIV”) is expected to enter Phase 1 studies in the second half of 2020. The Company is also planning to initiate 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.

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 (the “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.

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. The Chief Executive Officer, Chief Financial Officer, and other executives of ElevateBio also serve in similar management roles with AlloVir.

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

1. Nature of the Business (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 condensed consolidated financial statements are issued.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including preclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance and reporting capabilities. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The Company believes that its \$64.4 million of cash and cash equivalents and \$51.4 million of short-term investments held at March 31, 2020, are sufficient to fund planned operations for at least twelve months from the date that these condensed consolidated financial statements are available to be issued.

The accompanying condensed consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business. Through March 31, 2020, the Company has funded its operations primarily with proceeds received from capital contributions, research grants and from the sale of preferred stock. The Company has incurred recurring losses since its inception, including net losses attributable to AlloVir common stockholders of \$9.3 million for the three months ended March 31, 2020 and \$2.5 million for the three months ended March 31, 2019. In addition, at March 31, 2020, the Company had an accumulated deficit of \$64.7 million. The Company expects to continue to generate operating losses for the foreseeable future.

The accompanying condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty. Accordingly, the condensed 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

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

1. Nature of the Business (Continued)

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.

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.

Additionally, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (CARES Act). The CARES Act is an approximately \$2 trillion emergency economic stimulus package in response to the COVID-19 pandemic, which among other things contains numerous income tax provisions. Some of these income tax provisions are expected to be effective retroactively for years ending before the date of enactment. The Company is currently evaluating the impact of the CARES Act on its consolidated financial position, results of operations and cash flows.

2. Summary of Significant Accounting Policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the years ended December 31, 2019 and 2018 ("annual financial statements"), included elsewhere in this prospectus. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies, except as noted below.

Interim Financial Information

The accompanying condensed consolidated balance sheet at March 31, 2020, and the condensed consolidated statements of operations and comprehensive loss, statements of convertible preferred stock and changes in stockholders' deficit and statements of cash flows for the three months ended March 31, 2020 and 2019 are unaudited. The condensed consolidated interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which

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

2. Summary of Significant Accounting Policies (Continued)

include only normal recurring adjustments necessary for the fair presentation of the Company's financial position at March 31, 2020 and the results of its operations and its cash flows for the three months ended March 31, 2020 and 2019. The financial data and other information disclosed in these notes related to the three months ended March 31, 2020 and 2019 are also unaudited. The results for the three months ended March 31, 2020 are not necessarily indicative of results to be expected for the full year or for any other subsequent interim period.

Pro Forma Information

The accompanying pro forma condensed consolidated balance sheet at March 31, 2020 has been prepared to give effect, upon the closing of a qualified initial public offering, to the automatic conversion of all outstanding convertible preferred stock as of March 31, 2020, into 39,859,139 shares of common stock.

The pro forma basic and diluted weighted-average common shares outstanding used in the calculation of pro forma basic and diluted net loss per share attributable to common stockholders for the three months ended March 31, 2020 has been prepared to give effect, upon a qualified initial public offering, to the automatic conversion of all outstanding shares of preferred stock into common stock as if the proposed initial public offering had occurred on January 1, 2019, or the date of issuance, if later.

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 1, 2020 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.

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

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 condensed consolidated balance sheets:

(in thousands)	March 31, 2020			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. government treasury securities	\$ 51,110	\$ 244	\$ —	\$51,354
Totals	<u>\$ 51,110</u>	<u>\$ 244</u>	<u>\$ —</u>	<u>\$51,354</u>

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

Certain short-term debt securities with original maturities of less than 90 days are included in cash and cash equivalents on the condensed consolidated balance sheets and are not included in the tables above. At March 31, 2020 and December 31, 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)	March 31, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market fund	\$56,663	\$ —	\$ —	\$56,663
Demand deposit	—	—	—	—
Totals	<u>\$56,663</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$56,663</u>
Short-term investments:				
U.S. Government Treasury Bills and Bonds	\$51,354	\$ —	\$ —	\$51,354
Totals	<u>\$51,354</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$51,354</u>

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

4. Fair Value Measurements (Continued)

(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	<u>\$56,434</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$56,434</u>
Short-term investments:				
U.S. Government Treasury Bills and Bonds	\$64,993	\$ —	\$ —	\$64,993
Totals	<u>\$64,993</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$64,993</u>

During the three months ended March 31, 2020 and the year ended December 31, 2019, there were no transfers between levels. The fair values of the Company's cash equivalents, consisting of a money market fund and demand deposit, are based on quoted market prices in active markets with no valuation adjustment.

The Company uses the carrying amounts of its restricted cash, unbilled grants receivable, prepaid expenses and other current assets, accounts payable and accrued expenses to approximate their fair value due to the short-term nature of these amounts.

5. Leases

The Company leases an office space in Houston, Texas under an operating lease that expires in September 2020. The Company also sub-leases from ElevateBio a portion of its office space in Cambridge, Massachusetts on a month-to-month basis. 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.

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

2020 (remaining 9 months)	\$ 2,700
2021	3,600
2022	3,600
2023	2,100
Total lease payments	12,000
Less: interest (4.53% - 5.75%)	(993)
Total lease liability	<u>\$11,007</u>
Lease liability – current	\$ 3,107
Lease liability – long-term	<u>\$ 7,900</u>

Total rent expense was \$1.0 million and approximately \$29,000 for the three months ended March 31, 2020 and 2019, respectively. Cash paid for operating leases was \$1.2 million and \$0.2 million for the three months ended March 31, 2020 and 2019. The weighted average remaining lease term is 3.3 years at March 31, 2020. The weighted average discount rate is 5.14%.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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6. Accrued Expenses

Accrued expenses consisted of the following:

(in thousands)	March 31, 2020	December 31, 2019
Employee compensation and benefits	\$ 479	\$ 1,520
Professional fees	640	445
Research and development	1,091	3,051
Other	65	147
Total accrued expenses	<u>\$ 2,276</u>	<u>\$ 5,163</u>

7. Sponsored Research and License Agreements***Baylor College of Medicine***

In June 2019, the Company entered into a sponsored research agreement (“SRA-2”) with Baylor College of Medicine (“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 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. Under the License Agreement, the Company agrees to use commercially reasonable efforts to develop and commercialize the licensed products in the United States, Germany, Italy, France, Spain, the United Kingdom and Japan. The license expires on a country-by-country basis, on the later of (i) the date of expiration of the last valid claim of the patent rights to expire in such country or (ii) the first date following the tenth anniversary of the first commercial sale of such Licensed Product (defined as any product, process or service that incorporates, utilizes or is made with the use of the Subject Technology or Patent Rights) in such country. After such expiration, the Company will have a perpetual, paid-in-full license in such country.

In May 2020, the Company amended the License Agreement (the “License Agreement Amendment”), 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 License Agreement Amendment 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 License Agreement Amendment in its entirety at any time for convenience upon a certain number of days’ written notice. BCM may terminate the License Agreement Amendment in its entirety for the Company’s uncured material default.

ALLOVIR, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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7. Sponsored Research and License Agreements (Continued)

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 License Agreement Amendment, 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 License Agreement Amendment, 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 License Agreement Amendment, 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 License Agreement Amendment, BCM would be eligible to receive tiered sublicense income at percentage rates in the mid-single to low double-digits.

Collectively under the agreements above and for services provided by BCM the Company paid \$0.4 million and \$0.1 million during the three months ended March 31, 2020 and 2019, respectively, and the payments were classified in research and development expense in the condensed consolidated statements of operations and comprehensive loss.

Primarily all costs incurred related to services provided by BCM under License agreements and SRA-2 discussed above qualify for reimbursement under one of the Company's grants discussed in Note 8 and Note 9. Consideration received under the CPRIT Grant is recognized within grant revenue under ASC 606 in the condensed consolidated statements of operations and comprehensive loss. Reimbursements for qualifying expenses incurred under all other grants are recognized within other income, net in the condensed consolidated statements of operations and comprehensive loss.

8. 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 is three years beginning September 1, 2017 through August 31, 2020. This grant has a matching requirement where the Company is obligated to match 50% of the grant funds used on the project. In addition, the grant includes 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.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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8. Revenue (Continued)

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 three months ended March 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 three months ended March 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)	<u>Balance at Beginning of Period</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
Contract liabilities:				
Deferred revenue	\$ 2,663	\$ —	\$ (2,663)	\$ —

9. Funding Arrangements**SBIR GRANT**

In June 2017, the Company was awarded a Small Business Innovation Research ("SBIR") grant by the National Institute of Health ("NIH") in the amount of \$3.0 million. This grant is effective from September 15, 2017 to March 31, 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 reported by the Company to NIH. Under this grant, the Company received \$0.0 million and \$0.1 million during the three months ended March 31, 2020 and 2019, respectively. The Company recognized income of approximately \$48,000 and \$0.1 million on incurred expenses during the three months ended March 31, 2020 and 2019, respectively.

The SBIR grant does not fall within the scope of ASC 606 as NIH does not meet the definition of a customer, and the grant from NIH was 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 condensed consolidated statements of operations and comprehensive loss.

10. Convertible Preferred Stock and Stockholders' Deficit**Common Stock**

Upon consummation of the LLC Conversion, the Company issued one share of common stock to the Managing Member of the LLC. The voting, dividend and liquidation rights of the holders of the Company's common stock is subject to and qualified by the rights, powers and preferences of the holders of the preferred stock as set forth below.

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 Certificate of Incorporation.

ALLOVIR, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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10. Convertible Preferred Stock and Stockholders' Deficit (Continued)

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

	March 31, 2020
Preferred Stock, as converted	39,859,139
Unvested restricted stock units and stock options outstanding under the 2018 Equity Incentive Plan	4,215,266
Stock available for grant under the 2018 Equity Incentive Plan	426,092
	44,500,497

The Company had authorized 7,033,971 shares of common stock available for grant under the Company's 2018 Equity Incentive Plan (see Note 11). The summary of plan activity for shares issued and outstanding and the number of shares remaining available for grant under the plan are as follows:

	March 31, 2020
Common stock granted under the 2018 Equity Incentive Plan	6,607,879
Common stock available for grant under the 2018 Equity Incentive Plan	426,092
	7,033,971

As of March 31, 2020, there were 2,392,397 shares of common stock that were vested of the 6,607,879 shares of common stock granted under the 2018 Equity Incentive Plan.

Convertible Preferred Stock

At March 31, 2020 and December 31, 2019, preferred stock consisted of the following:

	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Value	Common Stock Issuable Upon Conversion
(in thousands, except share amounts)					
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	14,877,697	14,877,697	120,923	121,253	9,983,632
Total	79,398,350	59,398,350	\$ 173,127	\$ 188,034	39,859,139

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, have the following rights and preferences:

Voting

The holders of preferred stock are 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 be converted. The holders of a majority of the then outstanding preferred stock shall have 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.

ALLOVIR, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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10. Convertible Preferred Stock and Stockholders' Deficit (Continued)

Certain matters, prior to being able to be undertaken by the Company, require the affirmative vote of the holders of preferred stock, voting separately as a single class. These matters include 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 require 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.

As of March 31, 2020, the applicable conversion price of the Preferred Stock is \$2.24 for the Series A Preferred Stock and \$12.15 for the Series B Preferred Stock.

Conversion

At the option of the holder, all preferred stock is convertible into common stock at any time after the date of issuance. The initial conversion price is equal to the original issue price per share (\$1.50 for Series A Preferred Stock and \$8.15 for Series B Preferred Stock) and is subject to adjustment as disclosed in Certificate of Incorporation. Each preferred stock will automatically convert into common stock at an 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 are 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.

Liquidation Preference

In the event of a liquidation of the Company, the holders of Series B Preferred Stock shall 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 are insufficient to pay the Series B Preferred Stock, the holders of Series B Preferred Stock will 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 shall 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 are insufficient to pay the Series A Preferred Stock, the holders of Series A Preferred Stock will share ratably in the distribution of the assets based on the distribution that would have otherwise been paid in full.

Redemption

The Company has determined that all series of preferred stock are redeemable, based on the Certificate of Incorporation that states upon the occurrence of a deemed liquidation event, the holders of preferred stock are

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10. Convertible Preferred Stock and Stockholders' Deficit (Continued)

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 is required to issue additional preferred stock and ElevateBio is 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 represents 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 contain 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 at December 31, 2019 and 2018, the Company concluded that the fair value was *de minimis* based on the probabilities of such events occurring at such dates. The Company will reassess the fair value of such embedded derivative each reporting period and any changes in fair value will be recorded in the condensed consolidated statements of operations and comprehensive loss.

11. Stock-Based Compensation

2018 Equity Incentive Plan

On September 17, 2018, the Board of Directors and stockholders approved the 2018 Equity Incentive Plan. The 2018 Equity Incentive Plan allows for the issuance of up to 7,033,971 incentive or non-qualified stock options, restricted stock or restricted stock units, or unrestricted stock to employees, consultants or advisors of the Company which vest in accordance with the specific terms of each individual grant (generally over four-year periods). The number of stock options, restricted stock, or restricted stock units and unrestricted stock is subject to adjustment as a result of a reorganization, recapitalization, stock dividend, stock split, reverse stock split or other similar change in the Company's capital stock. At March 31, 2020, the Company had 4,215,266 shares of unvested restricted stock units and stock options outstanding and 426,092 shares available for grant under the 2018 Equity Incentive Plan.

Restricted Stock

The Company granted 56,635 and 99,642 shares of restricted stock to employees during the three months ended March 31, 2020 and 2019, respectively. Stock-based compensation expense recognized for the restricted stock granted was \$0.6 million and \$0.2 million for the three months ended March 31, 2020 and 2019, respectively.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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11. Stock-Based Compensation (Continued)

The following table summarizes restricted stock activity for the three months ended March 31, 2020:

	Restricted Stock	
	Shares	Weighted Average Grant Date Fair Value
Unvested as of January 1, 2020	4,403,148	\$ 1.87
Granted	56,635	3.01
Forfeited	—	—
Vested	(292,832)	1.52
Unvested as of March 31, 2020	4,166,951	\$ 1.89

The weighted average grant-date fair value of restricted stock granted during the three months ended March 31, 2020 was \$3.01 per share. At March 31, 2020, there was \$7.2 million of unrecognized stock-based compensation cost related to the restricted stock, which is expected to be recognized over a weighted average period of 3 years.

Stock Options

In October 2019, the Company granted 44,960 non-qualified stock options to a consultant, none of which vested in 2019 or the three months ended March 31, 2020. They vest over a four-year period and have a 10-year contractual term. There were no stock options granted during the three months ended March 31, 2019.

In February 2020, the Company granted 3,355 incentive stock options to an employee, none of which vested in the three months ended March 31, 2020. They vest over a four-year period and have a 10-year contractual term.

	Stock Options			Aggregate Intrinsic Value
	Shares	Weighted Average Exercise Price	Weighted Average Contractual Life	
Options outstanding as of January 1, 2020	44,960	\$ 3.01	9.5	—
Granted	3,355	3.01	9.8	—
Forfeited	—	—	—	—
Vested	—	—	—	—
Options outstanding as of March 31, 2020	48,315	\$ 3.01	9.6	—
Options exercisable at March 31, 2020	—	—	—	—
Options unvested and expected to vest at March 31, 2020	48,315	\$ 3.01	9.6	—

The weighted average grant-date fair value of stock options granted during the three months ended March 31, 2020 was \$2.17 per share. At March 31, 2020, there was approximately \$0.1 million of unrecognized stock-based compensation cost related to these stock options, which is expected to be recognized over 3.3 years.

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11. Stock-Based Compensation (Continued)

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

	Three Months Ended March 31, 2020
Expected term (in years)	6.25
Expected volatility	84%
Risk-free interest rate	1.65%
Expected dividend yield	—
Fair value of common stock	\$ 3.01

Stock-Based Compensation Expense

Stock-based compensation expense was as follows:

(in thousands)	Three Months Ended March 31,	
	2020	2019
Research and development	\$ 214	\$ 18
General and administrative	432	213
Total stock-based compensation expense	<u>\$ 646</u>	<u>\$ 231</u>

12. Income Taxes

The Company's income tax provision is computed based on the federal statutory rate and the average state statutory rates, net of the related federal benefit. For the three months ended March 31, 2020 and 2019, the Company did not record a current or deferred income tax expense or benefit due to current and historical losses incurred by the Company. The Company's losses before income taxes consist solely of losses from domestic operations.

The Company's estimate of the realizability of the deferred tax asset is dependent on estimates of projected future levels of taxable income. In analyzing future taxable income levels, the Company considered all evidence currently available, both positive and negative.

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13. Net Loss per Share and Pro Forma Net Loss Per Share

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company:

(in thousands, except share and per share data)	Three Months Ended March 31,	
	2020	2019
Numerator:		
Net loss	\$ (9,339)	\$ (2,524)
Net loss attributable to common stockholders – basic and diluted	<u>\$ (9,339)</u>	<u>\$ (2,524)</u>
Denominator		
Weighted-average common shares outstanding – basic and diluted	2,215,958	792,376
Net loss per share attributable to common stockholders – basic and diluted	<u>\$ (4.21)</u>	<u>\$ (3.19)</u>

At March 31, 2020 and 2019, the Company's potentially dilutive securities were preferred stock, unvested restricted stock and stock options, which have been excluded from the computation of diluted net loss per share attributable to common stockholders for the three months ended March 31, 2020 and 2019, as the effect would be to reduce the net loss per share attributable to common stockholders. Based on the amounts outstanding at March 31, 2020 and 2019, the Company excluded the following potential common shares from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	Three Months Ended March 31,	
	2020	2019
Series A1 Preferred Stock	—	13,420,970
Series A2 Preferred Stock	13,420,970	13,420,970
Series A3 Preferred Stock	15,067,706	—
Series A4 Preferred Stock	1,386,831	1,386,831
Series B Preferred Stock	9,983,632	—
Options to purchase common stock	48,315	—
Unvested restricted stock	4,166,951	3,420,611

Pro forma net loss per share attributable to common stockholders is computed using the weighted average number of common shares outstanding after giving effect to the conversion of all outstanding convertible preferred stock into common shares as if such conversion had occurred on January 1, 2019, or the date of issuance, if later.

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NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS—(Continued)
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13. Net Loss per Share and Pro Forma Net Loss Per Share (Continued)

Pro forma basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Three Months Ended March 31, 2020
Numerator:	
Net loss attributable to common stockholders	(9,339)
Net loss attributable to common stockholders – basic and diluted	<u>\$ (9,339)</u>
Denominator:	
Weighted-average common shares outstanding – basic and diluted	2,215,958
Pro forma adjustment to reflect automatic conversion of convertible preferred stock to common stock upon the completion of the proposed initial public offering	39,859,139
Pro forma weighted-average common shares outstanding – basic and diluted	<u>42,075,097</u>
Pro forma net loss per share attributable to common stockholders – basic and diluted	<u>\$ (0.22)</u>

14. 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. The Company incurred \$1.1 million and \$0.7 million of expenses during the three months ended March 31, 2020 and 2019, respectively, related to services provided to the Company by ElevateBio and affiliates. The Company owed ElevateBio \$0.5 million and \$0.2 million as of March 31, 2020 and December 31, 2019, respectively, which is recorded in Amount due to related party on the condensed consolidated balance sheets.

During the three months ended March 31, 2020 and 2019, members of the Company’s management received a total of \$0.3 million and \$0.1 million, respectively in consulting fees.

15. Subsequent Events

The Company has evaluated all subsequent events through June 3, 2020, the date the financial statements were available to be issued and through July 23, 2020, as it relates to the Reverse Stock Split. The following events occurred subsequent to March 31, 2020:

On May 12, 2020, the Company amended and restated the License Agreement with BCM (see Note 7), 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 additional technology developed by Baylor under SRA-2 since the original License Agreement was executed. The License Agreement amendment establishes royalties and milestones for the added pre-clinical products; on the SARS-CoV-2 product. Additionally, the Company is obligated to pay BCM \$3.0 million upon the FDA’s approval of a licensed product for the prevention and treatment of

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15. Subsequent Events (Continued)

SARS-CoV-2 as well as sales-based milestone payments of up to \$37.5 million for the sale of such licensed product.

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.

16,250,000 Shares



Common Stock

PROSPECTUS

Morgan Stanley

J.P. Morgan

SVB Leerink

Piper Sandler

July 29, 2020