UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2021

OR

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

Commission File Number 001-40703

Adagio Therapeutics, Inc.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-1403134**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1601 Trapelo Road, Suite 178 Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 819-0080

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	ADGI	The Nasdaq Global Market

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

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

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

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

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

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

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

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

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

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

The Registrant was not a public company as of the last business day of its most recently completed second fiscal quarter and therefore cannot calculate the aggregate market value of the voting and non-voting common equity held by non-affiliates as of such date.

The number of shares of the Registrant's Common Stock outstanding as of March 24, 2022 was 109,675,173.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive proxy statement, to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2022 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

Table of Contents

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of differentiated products for the prevention and treatment of infectious disease. We are developing our lead product candidate, adintrevimab, for the prevention and treatment of coronavirus disease 2019, or COVID-19, the disease caused by the virus SARS-CoV-2 and its variants. COVID-19 has caused the current global pandemic that remains a significant global health crisis and has resulted in millions of deaths and lasting health problems in many survivors. We believe that COVID-19 will become an endemic disease requiring a variety of effective, safe and convenient prevention and treatment options for years to come. We are leveraging our team's collective expertise and platform to deliver adintrevimab to patients and to discover novel solutions to infectious diseases through internal research and collaborations.

Adintrevimab is designed to be a potent, long-acting and broadly neutralizing antibody for both the prevention and treatment of COVID-19. We believe several key attributes combine to differentiate adintrevimab, including breadth, potency, durability of protection, convenient intramuscular, or IM, administration, and potential for broad application across multiple indications, depending on the SARS-CoV-2 variant.

Data from our Phase 1 healthy volunteer study ADG20-1-001 confirmed the extended half-life of adintrevimab, which we believe may allow for durable protection against COVID-19, depending on the variant. In February 2022, we expanded the Phase 1 study to evaluate safety and pharmacokinetics at higher doses. As of March 27, 2022, there were no study drug related adverse events, serious adverse events, injection-site reactions or hypersensitivity reactions reported across all dose levels evaluated.

We are assessing adintrevimab in two separate Phase 2/3 clinical trials: our EVADE trial to evaluate adintrevimab for the prevention of COVID-19 and our STAMP trial to evaluate adintrevimab for the treatment of COVID-19. Our EVADE clinical trial is a global Phase 2/3 clinical trial evaluating adintrevimab as a prevention for COVID-19 in both the post-exposure and pre-exposure settings. Our STAMP trial is our global Phase 2/3 clinical trial evaluating adintrevimab as a treatment for COVID-19. Due to the emergence and global spread of the Omicron variant, against which adintrevimab has reduced *in vitro* neutralization potency compared to prior variants, enrollment in both EVADE and STAMP was paused on January 11, 2022, and preliminary efficacy and safety data were evaluated in pre-and post-Omicron populations.

In the primary analysis population, patients infected with or exposed to a non-Omicron variant, or the pre-Omicron group, adintrevimab met the primary objectives across all three indications, demonstrating statistically significant and clinically meaningful efficacy. In pre-exposure and post-exposure prophylaxis, adintrevimab was associated with 71% and 75% relative risk reductions compared to placebo, respectively, in the prevention of RT-PCR confirmed symptomatic COVID-19. In an exploratory analysis of patients exposed to the Omicron variant, or the post-Omicron group, in pre-exposure prophylaxis, adintrevimab was associated with a clinically meaningful reduction in the risk of developing RT-PCR confirmed symptomatic COVID-19 compared with placebo. In treatment, adintrevimab was associated with a 66% relative risk reduction compared to placebo in the incidence COVID-19 related hospitalization or all cause death through Day 29 in the pre-Omicron group. In patients treated within three days of symptom onset, adintrevimab was associated with a reduced risk of COVID-19 hospitalization or death from any cause through Day 29 by 77% compared to placebo. A preliminary analysis of available safety data in each trial revealed a safety profile similar to that of placebo for adintrevimab.

We are also evaluating additional broadly neutralizing antibodies targeting the receptor binding domain, or RBD, as well as other subdomains within the spike protein for COVID-19. In addition, we plan to leverage the robust antibody discovery and development capabilities that have enabled our expedited advancement of adintrevimab into clinical trials to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza. In addition to building a portfolio of broadly neutralizing antibodies, we are leveraging our knowledge around broadly neutralizing antibody responses to inform the rational design of coronavirus vaccine antigens.

SARS-CoV-2 has given rise to a global pandemic that swept rapidly throughout the world in 2020. Of significant current concern is the continued emergence of a number of SARS-CoV-2 variants with increased transmissibility, pathogenicity, and/or the ability to evade neutralizing antibodies. In addition to the emergence of these variants, there are multiple factors that we believe contribute to the likelihood of COVID-19 becoming an endemic threat, including: (1) viral transmission before symptom onset; (2) uneven global rollout of vaccinations; (3) ongoing vaccine hesitancy; (4) limited duration of immunity conferred by both natural infection and vaccination; (5) limited vaccine efficacy against certain SARS-CoV-2 variants; (6)

uncertain impact of vaccines on transmission; and (7) variable implementation of virus mitigation behaviors, such as wearing masks and social distancing. We also believe that future pandemics similar to the COVID-19 pandemic are likely because, in many parts of the world, humans live in close proximity to animal species harboring coronaviruses that are capable of infecting humans.

Our vision is to discover, develop and commercialize differentiated products for the prevention and treatment of infectious diseases. To enable this vision, our current discovery efforts are focused on unique antibody-based product candidates that we optimize to improve breadth, potency, half-life, where applicable, and developability. Key elements that we believe differentiate our approach include: (1) recognition of the importance of and identification of broadly neutralizing antibodies; (2) industry-leading B cell mining, protein engineering and developability screening capabilities through our internal expertise and collaborations; and (3) reducing risk of clinical resistance.

Our Team

We were founded in June 2020 to develop a portfolio of anti-coronavirus antibodies discovered by Adimab, LLC, or Adimab, for both the prevention and treatment of COVID-19 and future emerging coronaviruses. Our founding scientists discovered adintrevimab, our lead product candidate, while working at Adimab, an industry leader in translating target hypotheses into therapeutically relevant antibodies. In order to maximize adintrevimab's potential and to facilitate its development and commercialization with appropriate infectious disease and development expertise and resources, we were launched as a new biotechnology company. Since our founding, we have assembled a team of industry veterans with substantial experience in discovering, developing and commercializing novel treatments for infectious diseases, including extensive experience discovering and optimizing monoclonal antibodies, or mAbs. Our leadership team has more than 100 years of combined development and commercialization experience with small and large molecules in infectious disease, as well as decades of domain expertise in B-cell immunology of viral diseases. Many of our team members have held senior positions at companies such as Pfizer Inc., Cubist Pharmaceuticals, Inc., Adimab, Biogen Inc. and Ironwood Pharmaceuticals, Inc., among others.

Our Strategy

Our goal is to discover, develop and commercialize differentiated products for the prevention and treatment of infectious diseases. In order to achieve this goal, our strategy involves execution of the following key elements:

- **Leverage our team's collective expertise in development, manufacturing and commercialization to deliver adintrevimab and future product candidates to patients.** Since our inception, we have assembled a team with deep and specific expertise in discovering, developing, manufacturing and commercializing novel treatments for infectious diseases, including extensive experience with developing mAb-based therapies. Based on our team's collective successful track record, we believe we will be able to execute on the clinical, regulatory, manufacturing and commercialization plan for adintrevimab, as well as any future programs.
- **Complete development and obtain regulatory authorization or approval for our lead product candidate, adintrevimab, for both the prevention and treatment of COVID-19**. Our clinical development plan for adintrevimab includes two global clinical trials designed to demonstrate the efficacy and safety of adintrevimab for the prevention and treatment of COVID-19. Our Phase 2/3 global clinical trial, EVADE, evaluates adintrevimab in the prevention of symptomatic COVID-19 in two separate populations: (1) individuals with known exposure to a person with laboratory-confirmed SARS-CoV-2 infection, also known as post-exposure prophylaxis, and (2) individuals who are at increased risk for SARS-CoV-2 infection, also known as pre-exposure prophylaxis, including those at increased risk of poor vaccine response. Similarly, our Phase 2/3 global clinical trial, STAMP, evaluates adintrevimab for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. Due to the emergence and global spread of the Omicron variant, against which adintrevimab has reduced *in vitro* neutralization potency compared to prior variants and uncertainty around the ability of the 300 mg dose of adintrevimab to prevent and treat disease due to the Omicron variant, enrollment in both EVADE and STAMP was paused on January 11, 2022. Data generated prior to pausing trials has been evaluated and may provide a path to a potential Emergency Use Authorization, or EUA, and/or Biologics License Application, or BLA, and commercialization, if adintrevimab is authorized and/or approved. As variants with varying degrees of neutralization activity to adintrevimab or other antibodies emerge over time, a variant based approach, including pharmacokinetics and pharmacodynamics/PD modeling, may be needed to support dose modification based on the *in vitro* potency of adintrevimab against the predominant circulating variants at any given time. We plan to file for EUA in the second quarter of 2022 and to discuss a potential path to BLA with the FDA and marketing authorization with health authorities outside the United States.

- **Successfully commercialize adintrevimab, if authorized or approved.** We believe adintrevimab will have several attractive attributes, including (1) broad application across multiple patient types, including pre- and post-exposure prophylaxis and treatment; (2) convenient IM dosing for use in the outpatient setting; (3) differentiated durability to protect the vulnerable, depending on the variant; (4) rapid onset of protection in the setting of post-exposure prophylaxis compared to vaccines; (5) standard refrigeration requirements to facilitate long term storage and distribution; and (6) long shelf life. Our plan for the commercialization of adintrevimab involves direct sales to governments, including relevant health agencies and national health systems, and in the United States, health insurers, integrated delivery networks and large employers. We intend to establish our own commercial organization in the United States, where we believe a focused commercial infrastructure will be able to successfully commercialize adintrevimab under a regulatory authorization and/or approval, and we are considering commercial options in Europe and beyond. In certain markets, such as Latin America, Asia-Pacific, including China, and Middle Eastern and African countries, we intend to commercialize adintrevimab through partnerships. For example, in July 2021, we entered into a license agreement with Biocon to combat COVID-19 in Southern Asia.
- **Ensure supply of drug product for adintrevimab and future clinical product candidates.** We have partnered with WuXi Biologics (Hong Kong) Limited, or WuXi, for advintrevimab clinical and commercial drug substance and drug product supply, and we have manufactured an initial supply of adintrevimab at commercial process scale. We believe we have secured sufficient capacity for our initial supply needs, in the event that adintrevimab is authorized under EUA. We continue to evaluate access to worldwide capacity at both WuXi and other contract development and manufacturing organizations, or CDMOs, to ensure we can meet expected future demand for advintrevimab. For future clinical product candidates, we plan to continue to use contract facilities for the development and good manufacturing practices, or GMP, manufacture of our products. CDMOs, including WuXi, will be evaluated for relevant capabilities, program suitability, and ability to meet desired timelines for candidate development. We expect to continue to use multiple contract CDMOs and laboratories to develop our pipeline candidates.
- **Advance differentiated product candidates to address infectious diseases through internal research, in-licensing and leveraging collaborations.** We have built a portfolio of broadly neutralizing SARS-CoV-2 antibodies as our lead disease area of focus. We have exclusive access to Adimab's unique B cell mining and protein engineering capabilities for coronavirus and influenza antibody discovery. We are currently leveraging this partnership and building internal capabilities to further expand our portfolio with additional uniquely differentiated anti-viral antibodies targeting COVID-19, as well as other infectious diseases. In addition, we have employed unique protein engineering strategies to significantly enhance adintrevimab activity against the Omicron variant and its sublineages. We are also collaborating with academic institutions on the discovery of vaccine immunogens that elicit broadly neutralizing antibodies to coronaviruses. Finally, we continue to evaluate product candidates for infectious diseases with high unmet medical need through in-licensing opportunities in addition to utilizing our team's expertise and differentiated design capabilities.

Background on Coronaviruses

Coronaviruses comprise a large family of viruses that are grouped into four genera: alphacoronavirus, betacoronavirus, gammacoronavirus and deltacoronavirus. Over the past 20 years, three pathogenic novel betacoronaviruses have spilled over into the human population from animal reservoirs to cause outbreaks of deadly pneumonia, including COVID-19, SARS and MERS. In many parts of the world, humans live in close proximity to animal species harboring sarbecoviruses, a lineage of betacoronaviruses that are capable of using human angiotensin-converting enzyme 2, or hACE2, receptors, and enabling infection in humans. In particular, bats are known to host such viruses, and large bat populations exist alongside humans in certain regions across the world, including eastern Europe, East Africa and southern China. Furthermore, bats are capable of carrying multiple sarbecoviruses, allowing for genetic recombination and the emergence of viral variants with higher propensity for transmission to humans. Current estimates suggest that between 6% and 23% of bats harbor viruses with such transmission potential. Not surprisingly, humans living in close proximity to bat populations have been infected by SARS-like coronaviruses. For example, approximately 0.5% to 3% of the rural population in southern China have antibody responses to these viruses, demonstrating past infection. This highlights the zoonotic nature of the sarbecovirus lineage, which includes both SARS-CoV-1 and SARS-CoV-2. Continued human intrusion into previously undeveloped habitats and increased exposure to these viral reservoirs are likely to result in more frequent occurrences of viral spillover, with potentially catastrophic consequences.

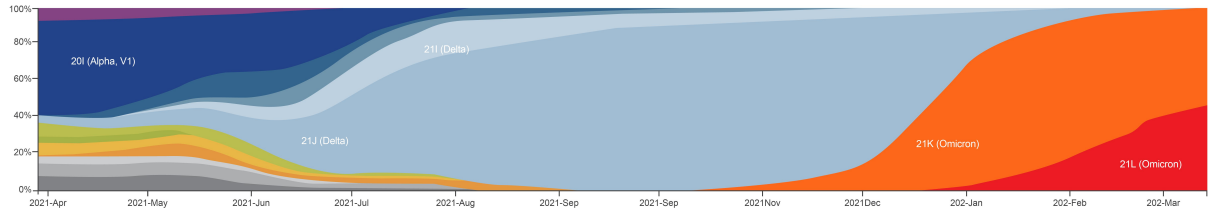
COVID-19, the disease caused by SARS-CoV-2 and its variants, has given rise to a global pandemic that swept rapidly throughout the world in 2020 and continues to cause infection and disease due to waning immunity and the continued emergence of resistant SAR-CoV-2 variants. The genome of SARS-CoV-2 encodes a spike, or S, protein, which is the surface

protein common to all members of the coronavirus family and mediates attachment and entry into host cells. The S protein is the only known target for neutralizing antibodies, and neutralizing antibodies to this protein are associated with protection from infection and disease. For this reason, the S protein is the primary target for currently available vaccines and therapeutic mAbs. Because the vast majority of potent neutralizing antibodies recognize epitopes overlapping the human ACE2 binding site on the RBD, most clinical-stage and EUA authorized SARS-CoV-2 antibodies target this antigenic region.

COVID-19 remains a significant global health crisis and case numbers continue to rise. According to estimates as of March 25, 2022 from the Johns Hopkins University, there have been approximately 478 million cases of laboratory-confirmed COVID-19 and 6.1 million COVID-19-related deaths worldwide, with approximately 80 million laboratory-confirmed cases of COVID-19 and more than 975,000 COVID-19-related deaths in the United States. Disease modeling conducted by several different organizations have further suggested that these estimates significantly undercount the true number of infections and deaths related to COVID-19.

Of significant current concern is the emergence of a number of SARS-CoV-2 variants with increased transmissibility, pathogenicity, and/or the ability to evade neutralizing antibodies. Variants of concern, or VOCs, include Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1); Delta (B.1.617.2) and Omicron (B.1.1.529/BA.1). Since their initial detection, some of these variants have spread rapidly worldwide, with confirmed cases in the United States, Canada and several European countries, indicating increased transmissibility relative to ancestral strains of SARS-CoV-2. As of March 19, 2022, the U.S. Centers for Disease Control and Prevention projected that the Omicron variant and its sub-lineages account for >99% of new COVID-19 cases in the United States. Importantly, several of the amino acid substitutions within the Omicron RBD are associated with escape from common classes of neutralizing antibodies, thereby endowing Omicron with significantly increased resistance to serum neutralizing antibodies induced following natural infection and vaccination with ancestral strains of the virus. Correspondingly, two doses of currently available vaccines have been shown to confer little to no protection against symptomatic disease caused by Omicron at >25 weeks post-vaccination. Homologous and heterologous BNT162b2 or mRNA-1273 booster immunization increases the level of protective efficacy to 60-70%, but this protection has been shown to wane over time. Due to its immune evasive properties, the emergence of the Omicron variant has been accompanied by a significant increase in SARS-CoV-2 breakthrough infections globally. Importantly, recent studies have shown that almost all clinical-stage and EUA authorized mAbs display significantly reduced or completely abolished activity against Omicron (BA.1) and/or its sublineages (BA1.1 and BA.2). Thus, there is an urgent need to develop next-generation mAbs that recognize current and future SARS-CoV-2 VOCs.

SARS-CoV-2 Variants Continue to Emerge Causing New Waves of Infections



In addition to the emergence of these variants, there are multiple factors that we believe contribute to the likelihood of COVID-19 becoming an endemic threat, including: (1) viral transmission before symptom onset; (2) uneven global rollout of vaccinations; (3) ongoing vaccine hesitancy; (4) limited duration of immunity conferred by both natural infection and vaccination; (5) limited vaccine efficacy against certain SARS-CoV-2 variants; (6) uncertain impact of vaccines on transmission; and (7) variable implementation of virus mitigation behaviors, such as wearing masks and social distancing.

Current Approaches for Prevention and Treatment of COVID-19 and Their Limitations

In response to the ongoing pandemic, multiple agents have been discovered, developed and authorized at an unprecedented speed to address COVID-19.

Vaccines for Prevention of COVID-19

Several vaccines have been approved for the prevention of COVID-19 both in the United States and abroad. These include mRNA-based vaccines, such as Moderna's mRNA-1273 and Pfizer/BioNTech's BNT162b2, and adenovirus-based vaccines, such as AstraZeneca's AZD1222, and Janssen's JNJ-78436735. While available COVID-19 vaccines have demonstrated meaningful efficacy in preventing symptomatic disease caused the original SARS-CoV-2 strain and early ancestral variants (e.g. D614G and Alpha), we believe additional solutions for the prevention of COVID-19 are required given considerable uncertainty around the future ability of vaccines to protect against disease and transmission, due to multiple factors, including:

- ***Limited efficacy against certain viral variants.*** While COVID-19 vaccines have demonstrated meaningful efficacy in preventing infection by the original strain of COVID-19, emerging evidence shows significantly lower levels of protection against certain variants. Multiple clinical and real-world studies have demonstrated reduced vaccine effectiveness against the Beta (B.1.351), Delta, and Omicron variants. For example, studies have shown that two doses of currently available vaccines confer little to no protection against symptomatic disease caused by the Omicron variant and its sub-lineages.
- ***Limited durability of response impacting the ability to achieve long term immunity.*** Due to a combination of waning antibody titers over time, the emergence of SARS-CoV-2 variants that display significantly reduced susceptibility to vaccine and infection-induced antibodies, and the limited level of mucosal immunity conferred by systemically administered vaccines, protection against symptomatic COVID-19 is relatively short-lived. As long as significant numbers of people globally are not protected against infection and transmission, SARS-CoV-2 variants will continue to circulate and cause disease.
- ***Unpredictable level of protection in immunocompromised individuals.*** Since vaccines leverage an individual's existing immune system to generate protection, vaccines may have little to no effectiveness against infection and disease in those who have compromised immune systems. Studies show that a subset of these individuals mount poor antibody responses to currently available mRNA vaccines, demonstrating the unmet medical need for effective preventative options for immunocompromised populations.
- ***Delayed onset of protection.*** The peak neutralizing antibody response conferred by currently available vaccines is usually 10 to 14 days after the final dose or booster vaccination, resulting in a period of time during which an individual is susceptible to SARS-CoV-2 infection and disease, despite having received the vaccine. Furthermore, given that certain vaccines require two doses, three to four weeks apart, full protection may not be achieved for several weeks after the initial dose.
- ***Vaccine hesitancy.*** Numerous surveys attribute vaccine hesitancy to a constellation of perceived safety, side effect and quality concerns. As of mid-March 2022, according to the CDC, only 65% of the total U.S. population was fully vaccinated and only 45% had received at least one booster. Globally, vaccine adoption and hesitancy are consistent with the U.S. figures. According to Our World in Data, as of mid-March 2022, 57% of the world population had been fully vaccinated.
- ***Availability and adoption in children.*** While children generally do not develop the severe consequences of COVID-19 seen in adults, studies have shown that they are still capable of transmitting SARS-CoV-2. Although an EUA was granted for use of the Pfizer/BioNTech vaccine in children ages five through eleven years, vaccine hesitancy by parents remains a potential obstacle to widespread adoption in school-aged children. Survey data collected in February 2022 by the Kaiser Family Foundation indicated that 41% of parents do not plan to or are waiting to see if they will vaccinate their children under 5-years old when vaccines first become available to them. This same survey indicated the percentage is 21% for children aged 5 to 11.

mAbs for Prevention or Treatment of COVID-19

Some SARS-CoV-2 mAb therapies have been granted an EUA in the United States for the prevention of symptomatic COVID-19. Bamlanivimab/etesevimab and casirivimab/imdevimab were granted an EUA for post-exposure prophylaxis for individuals at high risk for progression to severe COVID-19 who are not fully vaccinated or not expected to mount an adequate immune response to vaccines. Tixagevimab/cilgavimab is the only mAb product that has been granted an EUA for pre-exposure prophylaxis and is limited to use in individuals who have moderate to severe immune compromise and may not mount an adequate immune response to vaccines or from whom vaccination is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine. This product has also recently been recommended for authorization in EU member states by the European Medicines Agency.

Similarly, some SARS-CoV-2 mAb therapies, either as a monotherapy or a combination cocktail, have been granted an EUA in the United States or full marketing authorization in EU member states for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. Products granted an EUA include bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, sotrovimab and bebtelovimab; casirivimab/imdevimab, sotrovimab and regdanvimab have been granted marketing authorization in the EU.

Despite this progress in the availability of mAbs for the prevention and treatment of COVID-19, the clinical utility of some of these products has varied over time due to the emergence of SARS-CoV-2 variants demonstrating partial or full resistance to neutralization. The longevity of currently available mAbs for the prevention and treatment of COVID-19 is unknown due to the ongoing risk of the emergence of additional SARS-CoV-2 variants. For this reason, a broad range of mAb products are still needed for prevention and treatment of COVID-19 as waves of SARS-COV-2 variants continue to emerge over time.

Limitations of Currently Available mAbs

The COVID-19 pandemic has been characterized by waves of SARS-CoV-2 variants with increased transmissibility, pathogenicity, and/or the ability to evade neutralizing antibodies. Different variants have shown partial or full resistance to neutralization by certain currently available mAbs, leading to temporary pauses or permanent discontinuation of certain products and the need to alter dosing regimens for other products. For example, the FDA previously revoked the EUA for bamlanivimab as a single agent, and distribution of a second agent, bamlanvimab/etesevimab, was paused in the United States on June 25, 2021 due to lack of activity against the Gamma (P.1) and Beta (B.1.351) variants. Distribution of bamlanivimab/etesevimab subsequently resumed with the emergence of the Delta variant, against which this product retained *in vitro* neutralizing activity. The FDA subsequently halted the use of bamlanvimab/etesevimab and casirivimab/imdevimab in all U.S. regions on January 24, 2022 and halted the use of sotrovimab in certain U.S. regions on March 25, 2022 due to decreased *in vitro* neutralization activity against all or a subset of the Omicron variant lineage, leaving bebtelovimab as the only mAb product available for treatment in all U.S. regions as of March 26, 2022. Bebtelovimab is only recommended for use if none of the preferred therapies for high risk, non-hospitalized patients are available, feasible to deliver or clinically appropriate. On February 24, 2022, the FDA revised the EUA for tixagevimab/cilgavimab to increase the initial dose in response to reduced neutralization activity against some lineages of the Omicron variant. In addition, the use of currently available mAbs for the treatment of COVID-19 has been limited by the inconvenience of their intravenous, or IV, administration, which requires specialized facilities that are properly equipped to accommodate IV infusions in actively infected patients and may lead to a delay in administration. In Europe, IV administration in outpatient settings by community nurses or general practitioners remains very limited due to lack of appropriate infrastructure and sites of care. Additional factors that have limited use of mAbs include lack of awareness and education on appropriate use as well as perceived or genuine difficulty accessing treatment.

Antivirals for Treatment of COVID-19

Some antiviral products have been granted approval or EUA in the United States or marketing authorization in EU member states for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. Remdesevir, delivered as 3 days of intravenous therapy, is approved for this use in the United States and oral nirmatrelvir/ritonavir and molnupiravir have been granted an EUA. Remdesevir has been granted conditional marking authorization and nirmatrelvir/ritonavir has been granted full marketing authorization in the EU. Molnupiravir is currently not authorized for use in the European Union; the EMA's Committee for Medicinal Products for Human Use issued advice on the use of this agent for the treatment of COVID-19 to support national authorities, who may decide on possible early use of this medicine prior to marketing authorization.

Limitations of Currently Available Antivirals for the Treatment of COVID-19

Adoption of oral antivirals may be impacted by high pill burden, drug-drug interactions, limitations of use in certain populations and concerns about resistance. Adherence to the high pill burden of currently available oral agent's dosing regimens may be difficult for some patients. In addition, drug-drug interactions may complicate dosing, particularly for nirmatrelvir/ ritonavir, and this agent is also not recommended for use in patients for severe renal or hepatic impairment. Molnupiravir is currently recommended as a last-line agent due to low efficacy and is not recommended for use in pregnancy or patients less than 18 years of age. Use of remdesevir for outpatient treatment may be limited by the inconvenience of its multi-day IV dosing regimen. In addition, resistance is also a concern for all antivirals, as evidenced in HIV and hepatitis C.

Our Approach to The Development of Antibody-based Solutions for Coronaviruses and Other Infectious Diseases

Our vision is to discover, develop and commercialize differentiated products for the prevention and treatment of infectious diseases. To enable this vision, our current discovery efforts are focused on unique antibody-based product candidates that we optimize to improve breadth, potency, half-life, where applicable, and developability. We believe that mAb therapies with the following characteristics will have the potential to address the limitations of certain currently available mAbs used for the prevention or treatment of infectious diseases:

- High potency and broad neutralizing activity against circulating viral variants and future outbreaks caused by antigenically related viruses;
- Multiple mechanisms of action, including direct virus neutralization and elimination of infected host cells;
- Convenient outpatient administration as IM or subcutaneous administration; and
- Ability to provide both rapid and durable protection against disease.

To develop mAb therapies with these characteristics, we optimize both the antigen-binding fragment, or Fab, and constant fragment, or Fc, regions of candidate molecules to improve breadth, potency, half-life and developability. The Fab region binds to the viral antigen and is a key determinant of specificity and potency. The Fc portion binds to host cell receptors to activate the innate immune system to eliminate infected host cells and is a key determinant of serum half-life. Key elements that we believe differentiate our approach include:

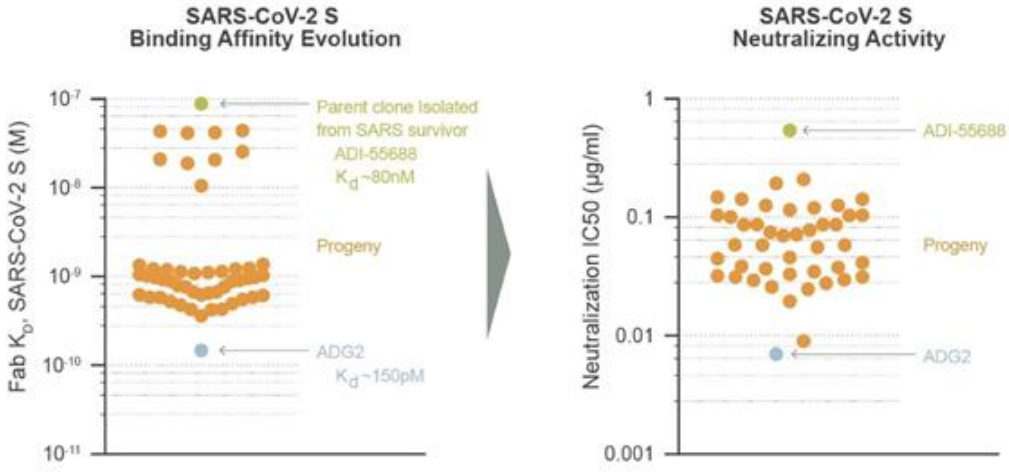
- **Recognition of the importance of and identification of broadly neutralizing antibodies:** From the outset for our COVID-19 program, we chose to focus on mAbs capable of broadly neutralizing not only SARS-CoV-2 and its variants, but also the entire viral class of sarbecoviruses that target the hACE2 receptor. Our rationale was driven by the recognition that COVID-19 is a continuation of previous human coronavirus outbreaks, including SARS and MERS, and the likelihood that future variants will continue to emerge and cause outbreaks in the human population. We are employing similar strategies for other antigenically variable viruses, such as influenza.
- **Industry-leading B cell mining, protein engineering and developability screening capabilities through internal expertise and our partnership with Adimab:** We leverage deep B cell mining capabilities to isolate broadly neutralizing antibodies from human donors and other *in vivo* sources. We then utilize protein engineering capabilities to improve the potency, breadth, biophysical properties, developability and half-life of the antibody candidates we advance into preclinical development. Where applicable, we specifically engineer our antibodies to extend their half-lives without affecting Fc-mediated innate immune effector activity. We also have the ability to engineer antibodies using alternative molecular formats, such as single domains or bispecifics, to further enhance functional activity.
- **Reducing risk of clinical resistance:** We are developing antibodies that target conserved residues on viral spike proteins, which are often important for viral fitness and therefore less likely to mutate. In addition, the residues that our antibodies recognize are not readily targeted by antibodies induced by natural infection, thus limiting immune pressure on these sites. Targeting of conserved sites that are subject to limited immune selection pressure reduces but does not fully eliminate the risk of circulating resistance. For these reasons, broadly neutralizing anti-coronavirus antibodies, including adintrevimab, have maintained neutralizing activity *in vitro* against most circulating SARS-CoV-2 variants described to date. In contrast, many SARS-CoV-2-specific antibodies, which bind to variable epitopes that are readily targeted by endogenous neutralizing antibodies, have shown reduced activity against several variants of concern.

Adintrevimab: An Example of B cell Mining and Protein Engineering Capabilities

We have employed this platform to discover adintrevimab. As the first step in the identification of advintrevimab, a blood sample was obtained from a survivor of the 2003 SARS outbreak who had never been exposed to SARS-CoV-2. The B cells were sorted based on reactivity to SARS-CoV-2, enabling us to isolate and identify 200 antibodies that bound to the SARS-CoV-2 S protein. Three of these antibodies were affinity engineered using the Adimab protein engineering platform. Affinity maturation allowed us to increase SARS-CoV-2 S protein binding affinity and neutralization potency by as much as 500- and 77-fold, respectively, as shown in the graphic below. Based on this enhanced profile, we selected ADG2, the progeny with the most improved binding affinity and neutralization potency, for further study. Additional preclinical studies indicated that ADG2 also exhibited highly potent activity against a panel of divergent SARS-like viruses, including SARS-CoV-1, WIV1 and SHC014, whereas the other clinical-stage antibodies demonstrated either limited potency or were non-neutralizing, or N.N., at the highest concentration tested, as shown in the graphic below. We further engineered ADG2 with an Fc region modification

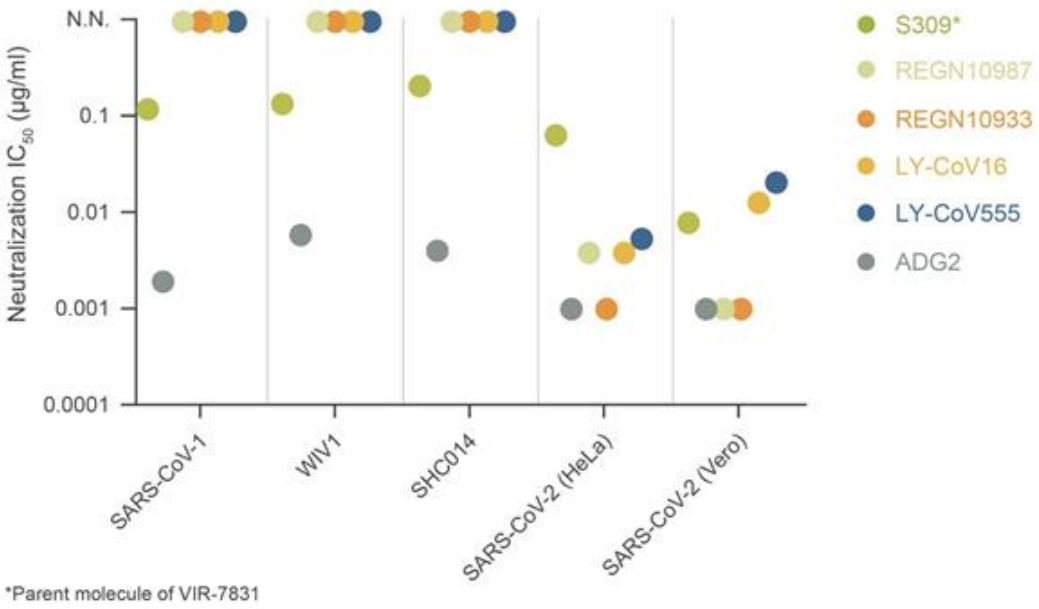
designed to extend the half-life to enable the potential for a single-dose administration to provide durable protection against symptomatic COVID-19 which resulted in our lead product candidate, adintrevimab.

Protein Engineering Substantially Improved Binding to and Neutralization of SARS-CoV-2



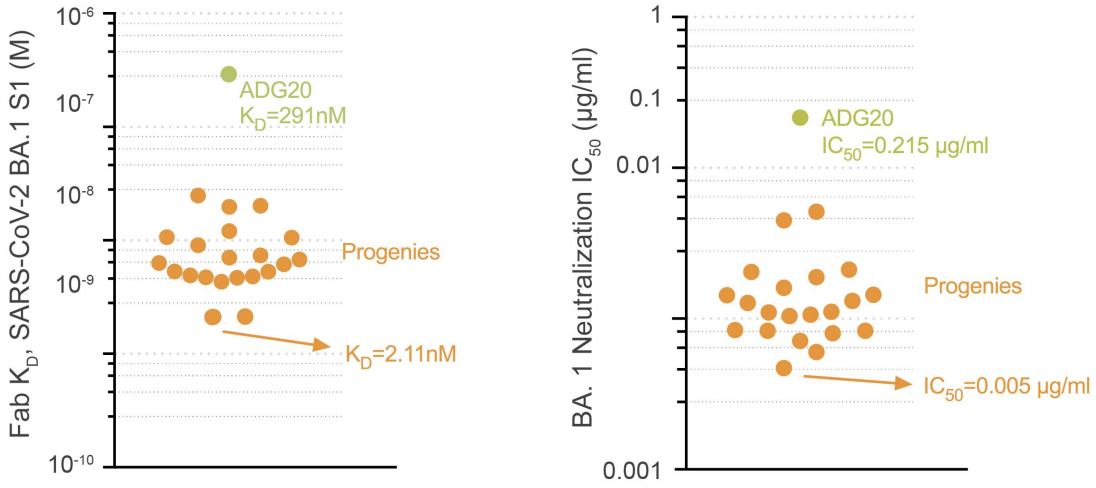
To determine whether ADG2 displayed broad neutralization, we evaluated its activity against additional members of the sarbecovirus lineage. Clade 1 of this lineage is of particular concern as it includes members that can infect human cells using the hACE2 receptor. We compared the activity of ADG2 with other currently available or clinical-stage mAbs against a subset of Clade 1 sarbecoviruses in authentic virus neutralization assays using transfected HeLa cells that express the hACE2 receptor and non-human primate Vero cells. ADG2 demonstrated high potency, defined as an IC_{50} value of 0.01 mcg/mL or less, against SARS-CoV-2 in the two different assays, whereas the potency of certain other antibodies was observed to vary. Importantly, ADG2 exhibited highly potent activity against the other Clade 1 viruses tested, including SARS-CoV-1, WIV1 and SHC014, whereas the other antibodies demonstrated either limited potency or were non-neutralizing, or N.N., at the highest concentration tested, as shown in the graphic below.

ADG2 Shows Broad Neutralization Activity Across Diverse SARS-Related Coronaviruses

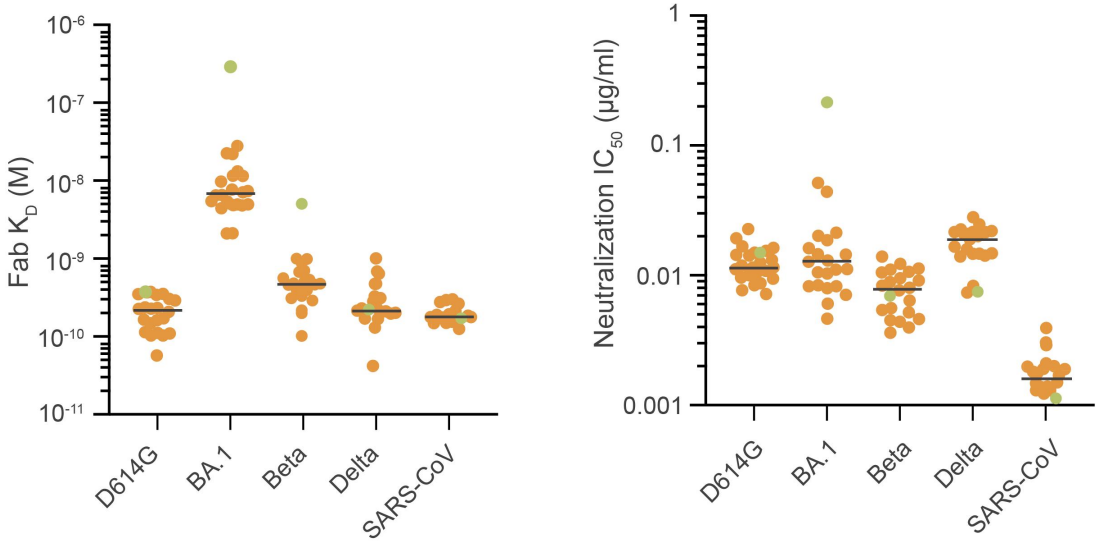


Subsequent work indicated that advintrevimab neutralized the Omicron BA.1 variant with reduced potency relative to previous SARS-CoV-2 VOCs (Alpha, Beta, Delta, and Gamma). We therefore employed our protein engineering platform to enhance advintrevimab activity against BA.1 while retaining activity against other SARS-CoV-2 VOCs. Within two months, we generated affinity matured versions of advintrevimab with over 100-fold improved binding affinity and up to 40-fold enhanced neutralization against BA.1 while maintaining activity against other VOCs and SARS-CoV. Thus, our unique B cell mining and protein engineering capabilities allow us to identify unique, functionally active clones that can be engineered and re-engineered for enhanced neutralization potency and breadth of recognition.

Protein Engineering Substantially Improved Binding and Neutralizing Activity of ADG20 (adintrevimab) Against Omicron/BA.1



Re-engineered ADG20 (adintrevimab) Progeny Maintain Binding and Neutralizing Activity Against Other SARS-CoV-2 Variants of Concern



Adintrevimab: Our Near-Term Solution for the Prevention and Treatment of COVID-19

Adintrevimab, our lead product candidate, is designed to be a potent, broadly neutralizing antibody for both the prevention and treatment of COVID-19, including disease caused by most variants, as either a single or combination agent. Unlike most other antibody-based therapies specifically targeting SARS-CoV-2, adintrevimab has demonstrated in non-clinical studies an ability to neutralize SARS-CoV-2, including most variants of concern, as well as a broad range of sarbecoviruses with neutralization IC_{50}s ranging from 0.004-1.1 mcg/mL in live-virus neutralization assays. In addition, adintrevimab has the

potential to be conveniently administered as an IM injection. We believe these and other attributes of adintrevimab differentiate it from some antibodies that are either available under EUA or in development to address COVID-19.

Our clinical development plan for adintrevimab includes a Phase 1 healthy volunteer single ascending-dose escalation study to establish safety, pharmacokinetics, and serum virus neutralizing antibody titers of adintrevimab and two global clinical trials designed to demonstrate the safety and efficacy of adintrevimab for the prevention and treatment of COVID-19, respectively. Our Phase 2/3 global clinical trial, EVADE, evaluates adintrevimab in the prevention of symptomatic COVID-19 in two separate populations: (1) individuals with known exposure to a person with laboratory-confirmed SARS-CoV-2 infection, also known as post-exposure prophylaxis, and (2) individuals who are at increased risk for SARS-CoV-2 infection, also known as pre-exposure prophylaxis, including those at increased risk of poor vaccine response. Similarly, we are evaluating adintrevimab for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression, in our Phase 2/3 STAMP trial.

Key Advantages of Adintrevimab

We believe adintrevimab will have the following key advantages:

- ***Broadly neutralizing activity across sarbecoviruses.*** From the outset, we selected and engineered the mAb that became adintrevimab specifically for its potential ability to broadly neutralize not only SARS-CoV-2 and the majority of SARS-CoV-2 variants of concern, but also additional members of the sarbecovirus lineage.
- ***Broad application across multiple patient indications.*** Adintrevimab has the potential to address pre- and post-exposure prophylaxis in addition to treatment of COVID-19, allowing governments and providers the flexibility to potentially use adintrevimab in the populations where it is most needed.
- ***Rapid onset of protection.*** As a mAb, adintrevimab has the potential to confer rapid protection post-dose against COVID-19 in the post-exposure setting.
- ***Differentiated durability.*** Adintrevimab has the potential to provide durable protection by virtue of its potency and half-life extension. Physiologically-based pharmacokinetic modeling has suggested that a single-dose 300 mg IM injection of adintrevimab will result in serum neutralizing titers that we believe may provide durable protection, depending on the variant. Duration of protection is especially important in the immunocompromised population who may remain unprotected by vaccines.
- ***Convenient, IM administration for use in the outpatient setting.*** Intravenous administration of currently available COVID-19 mAbs requires specialized facilities that are properly equipped to accommodate IV dosing in actively infected patients, which may lead to a delay in administration. In contrast, the low viscosity, high concentration formulation and potency of adintrevimab, allow it to be delivered as a convenient, IM injection in traditional outpatient settings.
- ***Potential for affordability.*** An antibody therapy that is administered by IM injection with potential durable protection, depending on the variant, has the potential to offer payors, providers and patients an affordable option to prevent and treat COVID-19. Initiatives by the Centers for Medicare & Medicaid Services to decrease out-of-pocket costs to patients and increase reimbursement for COVID-19 antibody therapies to providers underscore the importance of ensuring affordable access to COVID-19 antibodies. We believe adintrevimab's potential for affordability may allow for greater pricing flexibility to encourage broader access to adintrevimab and appropriate use by government and private payors, physicians and patients.
- ***Standard refrigeration requirements to facilitate worldwide distribution and storage.*** Adintrevimab may be conveniently stored and distributed under standard refrigerated conditions prior to administration. We anticipate that adintrevimab will be stable in sterile liquid form under refrigerated storage conditions and continue to confirm the long-term stability of adintrevimab.

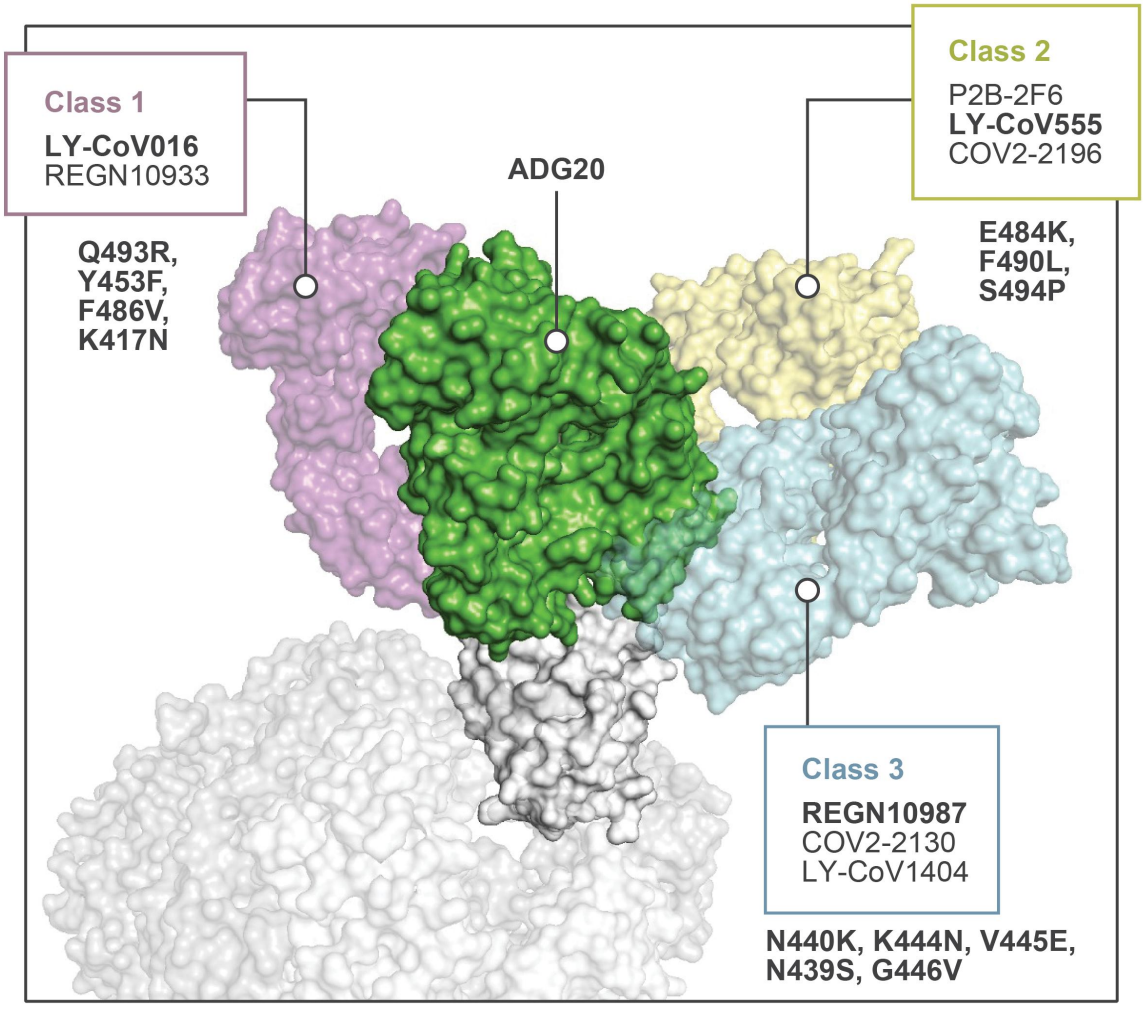
Mechanism of Action

Adintrevimab has the potential to impact viral replication and subsequent disease through multiple mechanisms of action, including direct neutralization of free virus and elimination of infected host cells through Fc-mediated innate immune effector activity. The majority of SARS-CoV-2-specific neutralizing antibodies target the RBD of the spike protein. Neutralizing anti-RBD antibodies that are commonly elicited by natural SARS-CoV-2 infection and vaccination (so-called "public" antibodies) have been categorized into three classes (class 1, 2, and 3) based on their convergent sequence features and binding epitopes. Public antibodies target amino acid residues that are variable among SARS-like coronaviruses, suggesting that they are less

likely to be important for viral fitness and are therefore more susceptible to mutation. Amino acid mutations that are present in multiple variants of concern, including those at positions E484, L452 and K417, confer resistance to many class 1 and class 2 antibodies, suggesting that these mutations emerged due to immune selection pressure by these types of antibodies. Because many clinical-stage and EUA authorized SARS-CoV-2 antibodies were identified from COVID-19 survivors and belong to one of these three public antibody classes, several of these mAbs display reduced activity against multiple SARS-CoV-2 variants of concern.

Adintrevimab recognizes an RBD epitope that is distinct from those targeted by public class 1-3 antibodies. The amino acid residues that adintrevimab engages are conserved among most bat SARS-like coronaviruses, which provides it with broadly neutralizing capabilities and suggests that these residues may be important to viral fitness, and thus less likely to mutate in the context of an infection. In addition, the binding site engaged by adintrevimab is not readily targeted by endogenous public antibodies, which limits immune pressure at these residues. A comparison of adintrevimab binding to the RBD of the SARS-CoV-2 S protein with that of Class 1-3 antibodies is illustrated in the molecular model presented below. Although adintrevimab displays reduced activity against the Omicron (BA.1) variant and lacks activity against the BA.2 sublineage relative to earlier variants of concern, the potency of neutralization shown *in vitro* against BA.1 is similar to or higher than that of most EUA approved SARS-CoV-2-specific antibodies that bind variable epitopes. Furthermore, unlike many other SARS-CoV-2-specific antibodies, adintrevimab has been shown *in vitro* to bind and neutralize the majority of SARS-CoV-2 variants of concern and variants of interest that have emerged to date. Thus, although Omicron variant and its sub-lineages have demonstrated that universal SARS-CoV-2 variant neutralization may not be feasible with anti-RBD antibody monotherapies, antibodies that show broad-spectrum activity against divergent sarbecoviruses are more likely to retain activity against emerging SARS-CoV-2 variants than antibodies with narrow activity.

Adintrevimab Targets a Unique Site on the RBD of the SARS-CoV-2 S Protein



In addition to neutralizing activity, adintrevimab displays Fc-mediated innate immune effector activity *in vitro*, including antibody-dependent cellular cytotoxicity, or ADCC, antibody-dependent cellular phagocytosis, or ADCP, and antibody-dependent complement deposition, or ADCD. We believe this mechanism of action may help to clear infected host cells *in vivo* and contribute to the control of SARS-CoV-2 infection.

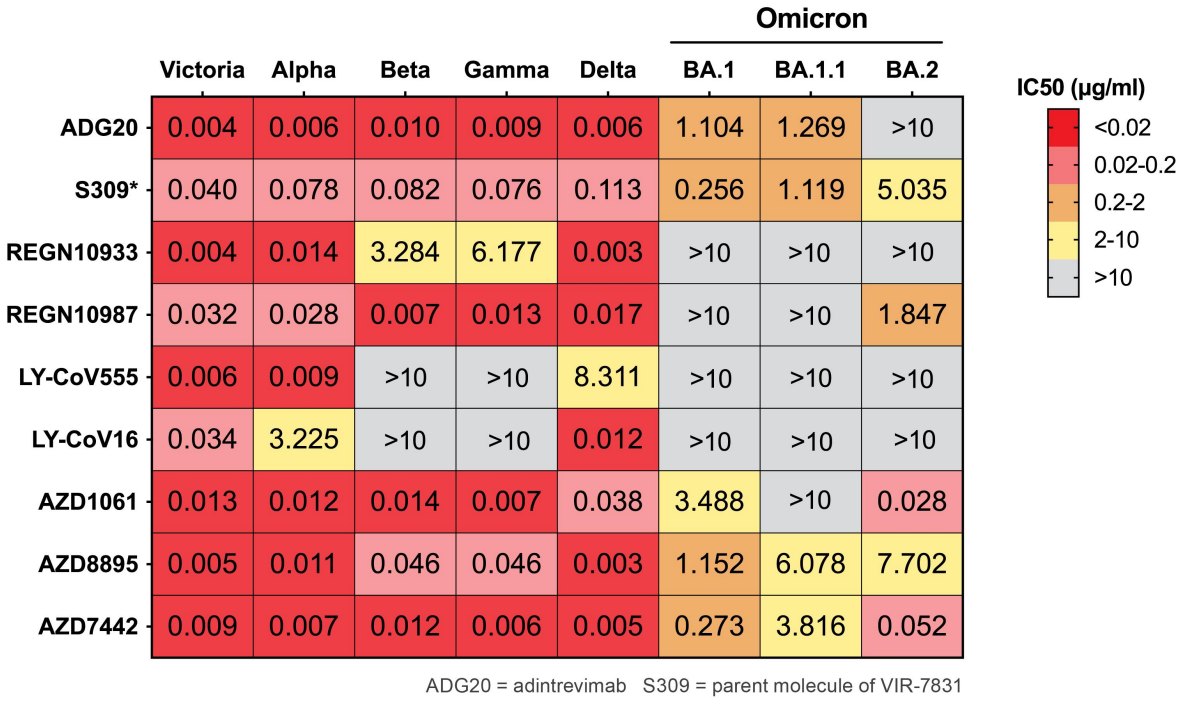
Preclinical Data

Adintrevimab has been evaluated in a series of *in vitro* and *in vivo* studies to demonstrate its potency and breadth as well as safety and efficacy in various animal models. *In vitro* binding studies have demonstrated that adintrevimab binds with high affinity to a diverse set of RBD subdomain 1, or RBD SD1, molecules from naturally circulating SARS-CoV-2 variants and related sarbecoviruses. Additional binding studies have indicated that the Fc modifications of adintrevimab confer enhanced affinity to non-human primate and human neonatal Fc receptors, or FcRn, at low pH, which has translated into a prolonged serum half-life in non-human primates due to enhanced recycling via FcRn. In *in vitro* studies, adintrevimab has demonstrated neutralizing activity against SARS-CoV-2 and most emerging variants that have been associated with lower efficacy rates of certain vaccines and are resistant or partially resistant to a subset of currently available or clinical-stage mAbs. In *in vivo* models, adintrevimab demonstrated an ability to prevent and treat SARS-CoV-2 infection and associated disease as well as a prolonged serum half-life. Prophylactic administration of ADG2 or adintrevimab provided protection against SARS-CoV-2 infection in three different animal models, and treatment with ADG2 reduced disease burden in animals infected with SARS-CoV-2.

In Vitro Studies of Adintrevimab Demonstrated Potency and Broad Neutralization of SARS-CoV-2 Against the Majority of Known Variants

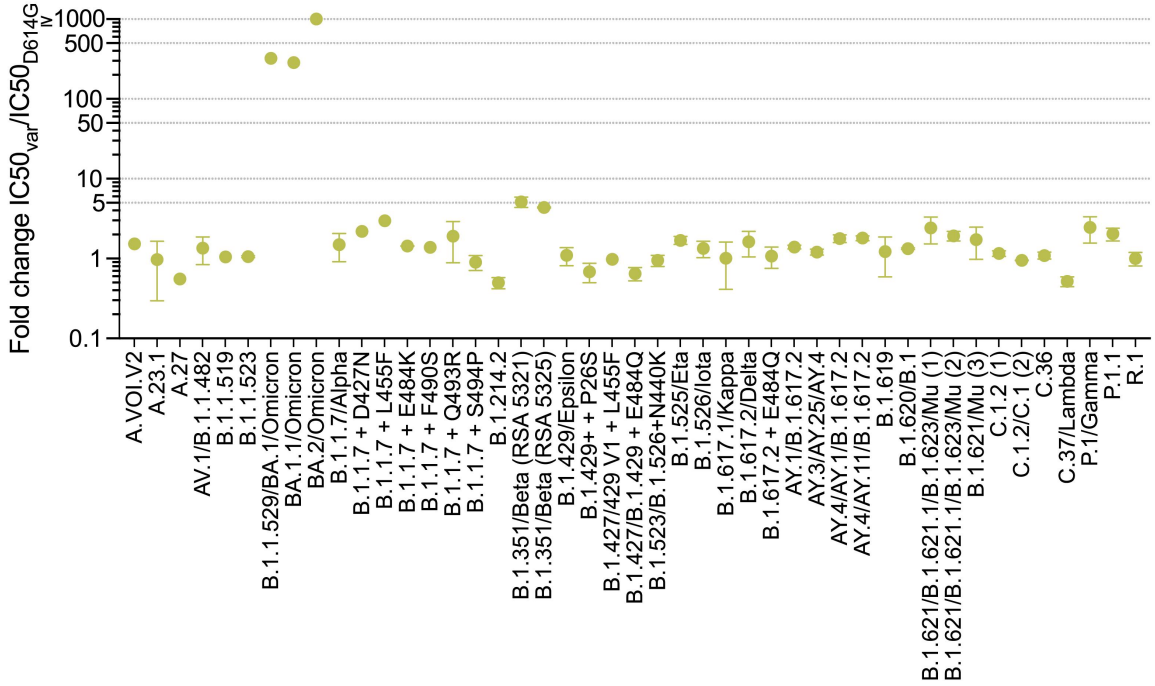
In an *in vitro* analysis conducted by an independent laboratory using authentic SARS-CoV-2 assays, we evaluated the potency and neutralizing activity of adintrevimab against the Victoria virus strain, which is similar to the original Wuhan-Hu-1 virus strain, Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Omicron (B.1.529 or BA.1) and two Omicron sub-lineages (BA.1.1 and BA.2) variants. Adintrevimab demonstrated potent viral neutralization activity (defined as an IC_{50} of 0.01 mcg/ml or less) against the original Victoria virus as well as the Alpha, Beta, Gamma, and Delta variants. In contrast, a subset of SARS-CoV-2-specific antibodies displayed substantial loss of neutralization activity against a subset of these variants, with IC_{50} values exceeding 1 mcg/mL. Adintrevimab also displayed neutralizing activity against the Omicron BA.1 and BA1.1 lineages, albeit with reduced potency (IC_{50} ~ 1 mcg/ml) relative to earlier SARS-CoV-2 strains but lacked detectable activity against the BA.2 lineage. Similarly, the majority of other clinical-stage or EUA authorized mAbs demonstrated significantly reduced or completely abolished activity against Omicron and its sublineages, thus highlighting the remarkable immune evasive properties of this particular variant of concern.

Adintrevimab Displays Neutralizing Activity Against Most SARS-CoV-2 Variants of Concern



The neutralization potency and breadth of adintrevimab was also evaluated by an independent U.S. government laboratory against a panel of 64 SARS-CoV-2 pseudovirus variants. We utilized the non-clinical and pre-clinical services program offered by the National Institute of Allergy and Infectious Diseases to generate this data. Variants tested included spike proteins encoding the full sets of mutations observed in emerging variants of concern and variants of interest. As shown in the graphic below, adintrevimab displayed neutralization activity across most variants tested to date.

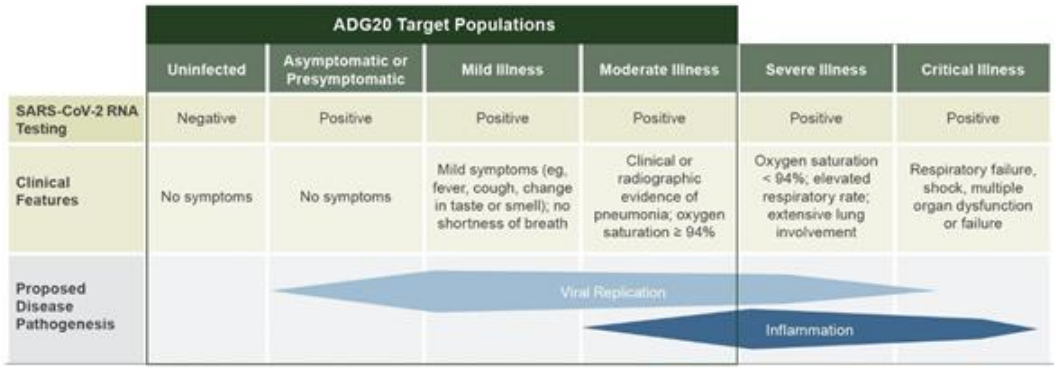
Adintrevimab Displayed Neutralization Activity Against Most SARS-CoV-2 Variants



Clinical Development

As shown in the graphic below, we believe that intervention with an antiviral neutralizing antibody before exposure to SARS-CoV-2, post-exposure but prior to the onset of symptoms or early in the course of symptomatic disease when viral replication is high but before the onset of significant immune pathology is likely to provide the greatest benefit to patients. This belief is supported by clinical experience with SARS-CoV-2 mAbs as well as prior experience with the use of neutralizing antibodies for the prevention and treatment of other respiratory virus infections such as influenza and respiratory syncytial virus, or RSV. For these reasons, our clinical development strategy is focused on prevention and early treatment of COVID-19 with the goal of preventing severe disease and its sequelae.

Adintrevimab: In Development for Prevention and Treatment of COVID-19



As shown below, our clinical development plan for adintrevimab includes a series of clinical trials to demonstrate the potential of adintrevimab for both the prevention and treatment of COVID-19 in adults and adolescents. We initiated our clinical program with a Phase 1 healthy volunteer single ascending-dose escalation study to establish safety, pharmacokinetics, and serum virus neutralizing antibody titers of adintrevimab over a period of 12 months. This study also provided preliminary safety and pharmacokinetic data at the 300 mg IM dose to support progression to Phase 2/3 trials. Our Phase 2/3 global clinical trial, EVADE, evaluates adintrevimab in the prevention of symptomatic COVID-19 in two separate populations: (1) individuals with known exposure to a person with laboratory-confirmed SARS-CoV-2 infection, also known as post-exposure prophylaxis, and (2) individuals who are at increased risk for SARS-CoV-2 infection, also known as pre-exposure prophylaxis, including those at increased risk of poor vaccine response. Our Phase 2/3 global clinical trial, STAMP, evaluates adintrevimab in the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. Follow-up in all three trials is ongoing and preliminary results are presented below across all populations studied.

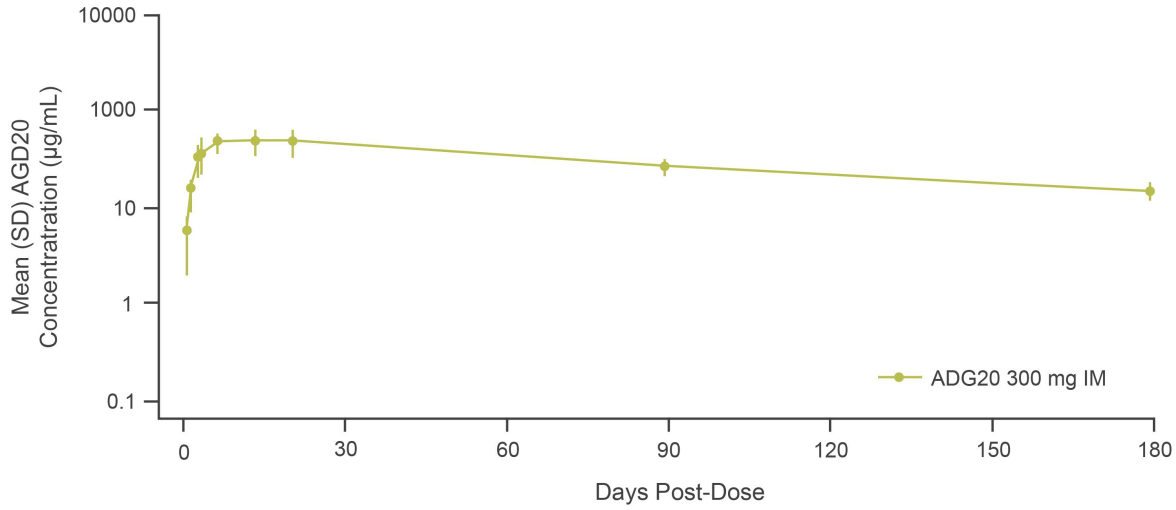
Our Clinical Development Program for Adintrevimab

	First-in-Human Trial	Prevention Trial EVADE	Treatment Trial STAMP
Population(s)	Healthy adult participants with no evidence of prior or current SARS-CoV-2 infection	Individuals with either: (1) reported, recent exposure to a person with laboratory confirmed SARS-CoV-2 infection (post-exposure prophylaxis); OR (2) increased ongoing risk of SARS-CoV-2 infection, including individuals unlikely to respond to vaccines (pre-exposure prophylaxis)	Ambulatory patients with mild or moderate COVID-19 and high risk of disease progression based on age or co-morbid conditions (eg, obesity, diabetes, chronic kidney disease)
Primary Endpoint(s)	Safety and tolerability of single IM and IV doses of ADG20	RT-PCR confirmed symptomatic COVID-19 through Day 28 (post-exposure) or 3 months (pre-exposure)	COVID-19 related hospitalization or all cause death through Day 29

First-in-Human Phase 1 Dose Escalation Clinical Trial

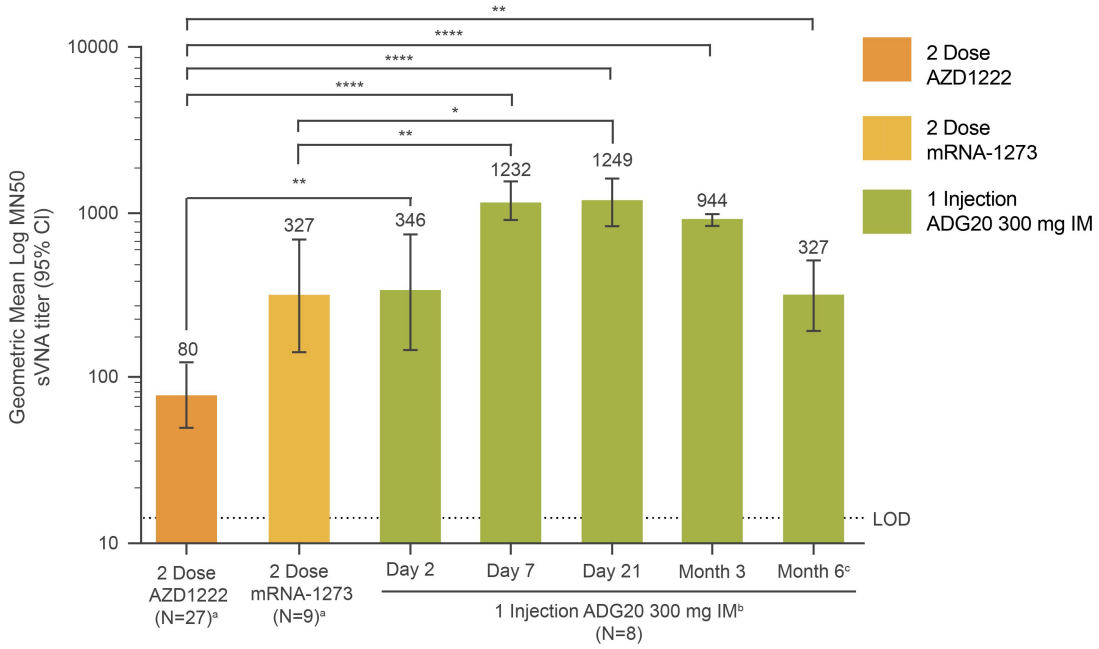
In February 2021, we initiated a Phase 1 single ascending-dose escalation clinical trial (ADG20-1-001), which is designed to evaluate the safety, tolerability and pharmacokinetic properties of adintrevimab, along with serum virus neutralizing antibody titers. We completed enrollment of 30 healthy volunteers across three cohorts in March of 2021, with ten participants per cohort randomized 8 to 2 to adintrevimab or placebo, respectively. Each participant received a single dose of either 300 mg IM, 500 mg IV or 600 mg IM of adintrevimab or placebo. Data from a six-month evaluation timepoint confirmed the extended half-life of adintrevimab, which approached 100 days based on the 300 mg IM dose cohort and we believe may allow for durable protection, depending on the SARS-CoV-2 variant. As of March 28, 2022, there were no study drug related adverse events, serious adverse events, injection-site reactions or hypersensitivity reactions reported through 12 month follow-up across the majority of participants in all three initial cohorts. Due to the reduction in neutralizing activity of adintrevimab against the Omicron variant and the potential for higher doses to overcome this shift in potency as well as address potential future SARS-CoV-2 variants, the Phase 1 study was amended in February 2022 to evaluate safety and pharmacokinetics of higher doses of adintrevimab. Preliminary safety data through two weeks post dosing suggest a favorable safety profile at the 1200 mg dose administered IM or IV with no study drug related adverse events, serious adverse events, injection-site reactions or hypersensitivity reactions reported. A population pharmacokinetic model based on the Phase 1 healthy volunteer data from the initial dose cohorts supported the extended half-life of adintrevimab and showed high bioavailabity (92%) following IM administration.

Preliminary Pharmacokinetic Profile of a Single 300 mg IM Dose of Adintrevimab at 6 Months



Serum virus neutralizing antibody titers are believed to be a key correlate of protection against COVID-19. In an exploratory analysis using an authentic virus neutralization assay, we compared serum virus neutralizing antibody titers on days 2, 7 and 21, and months 3 and 6 following a single 300 mg IM dose of adintrevimab to titers achieved 7 to 31 days, corresponding to peak titers, following administration of two doses of the AZD1222 or mRNA-1273 vaccine. As illustrated in the graphic below, by day 2 or the day following administration of a single 300 mg IM dose of adintrevimab, measured serum neutralizing antibody titers against the D614G strain were similar to peak serum neutralizing antibody titers induced by the mRNA-1273 COVID-19 vaccine and significantly exceeded peak titers generated by the AZD1222 vaccine. By day 7, serum neutralizing antibody titers for adintrevimab were significantly higher than peak titers generated by either vaccine and at month 6, neutralizing antibody titers were similar to the level of peak serum neutralizing antibody titers induced by the mRNA-1273 COVID-19 vaccine. These data further support the potential for a single 300 mg IM injection of adintrevimab to provide durable protection against COVID-19, depending on the SARS-CoV-2 variant.

Preliminary Serum Virus Neutralizing Titers After of a Single 300 mg IM Dose of Adintrevimab at 6 Months



[a]Vaccine timepoint: 7 to 31 days post 2nd dose; [b]adintrevimab recipients only; [c] Excludes samples taken following SARS-CoV-2 vaccination. Samples above upper limit of quantification (ULOQ) imputed to ULOQ. LOD=limit of detection; *P £ 0.05;**P £ 0.01; ****P £ 0.0001 (2-tailed Mann-Whitney U test; nominal p values shown).

Combined Phase 2/3 EVADE Trial of Adintrevimab for the Prevention of COVID-19

Our combined Phase 2/3 EVADE clinical trial of adintrevimab evaluates the safety and efficacy of adintrevimab in the prevention of symptomatic COVID-19 in two independent trial populations: (1) individuals with known exposure to a person with laboratory-confirmed SARS-CoV-2 infection, which we refer to as post-exposure prophylaxis, and (2) individuals who are at increased risk for SARS-CoV-2 infection, which we refer to as pre-exposure prophylaxis. The eligible trial populations also include individuals at risk of generating poor vaccine response, such as those who are immunocompromised. Our EVADE trial is designed as a randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy of a single IM dose of adintrevimab in preventing COVID-19, with an original target enrollment of approximately 6,400 individuals across both populations in the United States and other countries. We initiated enrollment in our EVADE trial in April 2021 and expanded enrollment to adolescents in the Phase 3 portion of both populations after iDMC review of safety data from the first 200 adult participants across both populations in the Phase 2 portion of the trial on August 24, 2021. We subsequently paused enrollment on January 11, 2022, due to the emergence and global spread of the Omicron variant, against which adintrevimab has reduced *in vitro* neutralization potency and, at the time, the 300 mg dose was thought to be unlikely to provide durable protection against COVID-19 due to the Omicron variant. At the time of the enrollment pause, a total of 487 participants were enrolled in the post-exposure cohort and 2,101 participants were enrolled in the pre-exposure cohort. The primary endpoint for these cohorts is the proportion of participants with laboratory-confirmed symptomatic COVID-19 through Day 28 and 3 months, respectively. The primary efficacy endpoint for pre-exposure prophylaxis was adjusted to 3 months, compared to the original planned follow-up period of 6 months, to allow assessment of efficacy against the Delta variant prior to widespread emergence of Omicron. All participants will be followed in both cohorts through 14 months for safety. Some of our clinical trial sites are located in Ukraine and we are monitoring the current conflict in this region to evaluate any potential impact to the trial.

Of the 487 participants randomized in the post-exposure cohort, 348 were included in the primary efficacy population, which included all randomized participants without evidence of current SARS-CoV-2 infection and who were randomized prior to November 30, 2021. In the primary efficacy analysis, adintrevimab was associated with a statistically significant lower incidence of SARS-CoV-2 RT-PCR positive symptomatic COVID-19 through Day 28 compared with placebo (3/173, 1.7%

vs. 12/175, 6.9%, respectively). The standardized risk difference was -4.9% (95% CI: -8.8, -1.0; p=0.0135), demonstrating a 75% relative risk reduction in favor of adintrevimab through 28 days or the emergence of Omicron, whichever was earlier. There were two (1.1%) COVID-19 related hospitalizations in the placebo group compared to none in the adintrevimab group. Of the 2,101 participants enrolled in the pre-exposure cohort, 1,433 were included in the primary efficacy population, which included all randomized participants without evidence of current or prior SARS-CoV-2 infection and who were randomized prior to November 30, 2021. In the primary efficacy analysis, adintrevimab was associated with a statistically significant lower incidence of SARS-CoV-2 RT-PCR positive symptomatic COVID-19 compared with placebo through Month 3 or the emergence of Omicron (12/730, 1.6% vs. 40/703, 5.7%). The standardized risk difference was -4.0% (95% CI –6.0, -2.1; p < 0.0001), demonstrating a 71% relative risk reduction in favor of adintrevimab through 3 months or the emergence of Omicron, whichever was earlier. There were 5 (0.7%) COVID-19 related hospitalizations in the placebo group compared to none in the adintrevimab group.

We also conducted an exploratory analysis of participants enrolled after November 30, 2021 and who were at risk of exposure to Omicron through the data cut-off date of March 2, 2022. In the small number of participants in the post-exposure prophylaxis population randomized post-Omicron, adintrevimab was not associated with a benefit in the reduction of RT-PCR-confirmed symptomatic COVID-19 through Day 28. In a pre-specified exploratory analysis of the pre-exposure prophylaxis cohort, which included 402 participants (196 and 206 in the adintrevimab and placebo groups, respectively) randomized after November 30, 2021 and followed after the emergence of Omicron (BA.1), a clinically meaningful reduction in the risk of developing RT-PCR confirmed symptomatic COVID-19 was observed with adintrevimab, as compared to placebo. Adintrevimab was associated with a relative risk reduction of 59% and 47% with a median follow-up duration of 56 and 77 days, respectively (nominal p <0.05).

A preliminary analysis of available safety data across both cohorts through March 2, 2022 with a median follow-up duration of 140 days for the pre-exposure cohort and 126 days for the post-exposure cohort in 1,239 adintrevimab treated participants revealed a similar safety profile to that of placebo. The incidence of adverse events, including serious adverse events, was similar between the adintrevimab and placebo groups. No study drug related serious adverse events, including no study drug related adverse events leading to death, were reported. The most frequently reported adverse events were solicited injection site reactions, the majority of which were mild or moderate in severity and occurred with similar frequency in both groups. One mild hypersensitivity reaction of mild urticaria was reported in an adintrevimab treated participant.

Combined Phase 2/3 STAMP Trial of Adintrevimab for the Treatment of COVID-19

Our STAMP combined Phase 2/3 clinical trial evaluates adintrevimab for the treatment of COVID-19 in ambulatory adult patients with mild to moderate disease who are at high risk of disease progression. Our STAMP trial is designed as a double-blind, randomized, placebo-controlled clinical trial to evaluate the efficacy of a single IM dose of adintrevimab compared to placebo in preventing COVID-19-related hospitalization or all-cause death through Day 29, with an original target enrollment of approximately 1,100 patients, all of whom were to be enrolled outside of the United States. We initiated enrollment in our STAMP trial in July 2021 and expanded enrollment to adolescents after iDMC review of safety and preliminary efficacy data from the Phase 2 portion of the trials on December 21, 2021. We subsequently paused enrollment on January 11, 2022 due to the emergence and global spread of the Omicron variant, against which adintrevimab has reduced *in vitro* neutralization potency and was thought to be unlikely to provide benefit for disease due to this variant. At the time of the enrollment pause, a total of 399 participants were randomized in the trial. The primary objectives of this clinical trial are to assess the safety and efficacy of adintrevimab compared to placebo in the prevention of COVID-19-related hospitalization or death through Day 29. All participants will be followed through 14 months for safety. Some of our clinical trial sites are in Ukraine and we are monitoring the current conflict in this region to evaluate any potential impact on the trial.

Of the 399 participants randomized in the trial, 336 were included in the primary efficacy population, which was defined as all randomized participants with COVID-19 due to non-Omicron SARS-CoV-2 variants, as determined by whole genome sequencing or epidemiology. In the primary analysis of efficacy, adintrevimab met statistical significance and was associated with a lower incidence of COVID-19 related hospitalization or all cause death through Day 29 compared with placebo (8/169, 4.7% vs. 23/167, 13.8%). The standardized risk difference was -8.6 % (95% CI: -14.65, -2.57; p=0.0052), demonstrating a 66% relative risk reduction in favor of adintrevimab. There was 1 (0.6%) death in the adintrevimab group, compared with 6 (3.6%) deaths in the placebo group through Day 29. In patients treated within three days of symptom onset, adintrevimab was associated with a reduced risk of COVID-19 hospitalization or death from any cause through Day 29 by 77% compared to placebo, 3.3% (3/91) in the adintrevimab group compared to 14.1% (12/85) in the placebo group. An exploratory analysis of efficacy was conducted in the small number (N=63; 29 in the adintrevimab group and 34 in the placebo group) of participants with COVID-19 due to the Omicron SARS-CoV-2 variant. There were two events of COVID-19 related hospitalization and no deaths through day 29; both events of hospitalization occurred in the placebo group. The sample size was too small to draw any conclusion regarding the efficacy of adintrevimab for the treatment of COVID-19 due to the Omicron variant.

An analysis of available safety data through February 2, 2022 with a median duration of follow-up of 73 days in the 192 participants in the adintrevimab group revealed no safety concerns for adintrevimab. The incidence of adverse events, including serious adverse events, was lower in the adintrevimab group compared to the placebo group. No study drug related serious adverse events, including no study drug related adverse events leading to death, were reported. The most frequently reported adverse events were solicited injection site reactions, all of which were mild or moderate in severity and occurred with similar frequency in both groups.

Regulatory Strategy

Based on the available data from EVADE and STAMP, we plan to request an EUA in the second quarter of 2022 for the use of adintrevimab in pre- and post-exposure prophylaxis as well as in the treatment of mild to moderate COVID-19 in high-risk individuals. We also plan to discuss the path to a biologics license application, or BLA, for adintrevimab with the FDA in the second quarter of 2022 and to determine the path to marketing authorization with regulatory authorities outside the United States.

Pediatric Clinical Development Plan

Similar to our strategy for the adult and adolescent populations, we anticipate generating data to support the use of adintrevimab for both the prevention and treatment of COVID-19 in the pediatric population. We currently have an aligned clinical plan with the FDA to evaluate adintrevimab as a preventative and treatment option in the pediatric population, with a trial in individuals between two and eleven years of age. The pediatric study plan may need to be modified following BLA discussions with the FDA. We believe adintrevimab has the potential to provide a treatment option for children at high risk of severe disease and be a viable prevention option for high risk children, such as those with moderate to severe immunocompromise who generate suboptimal vaccine responses.

Commercial Opportunity

Market Opportunity

Emergency Use Authorization (EUA) Environment

In an EUA environment where the federal government signs an Advance Purchase Agreement, or APA, with a manufacturer for a specific number of doses at a fixed price, product distribution is overseen by federal and state governments and product is ordered by institutions, prescribed by physicians and administered in a variety of settings. Product is free to the institutions and patients, but patients can be billed for administration costs. Currently, all oral antivirals and monoclonal antibodies are made available under APAs. Only Gilead's intravenous antiviral, remdesivir, which received full FDA approval for treatment of non-hospitalized patients (12 years of age or older) at high risk for COVID-19 disease progression in January 2022, is available under a standard purchase model where hospitals, clinics, and other institutions purchase product through distributors.

In an EUA environment where the federal government does not sign an APA, the manufacturer sells product directly to wholesalers and/or distributors who ship the product to various sites of care, and provider institutions and clinics can bill health plans for product. GlaxoSmithKline and Vir Biotechnology’s sotrovimab was granted an EUA in May 2021 but did not receive an APA until November 2021. In an EUA, a manufacturer cannot make any claims about the safety and efficacy of its drug; with a full marketing authorization/BLA, a manufacturer can make these claims as long as they are consistent with the product’s label.

If we are successful with our request for emergency use authorization of adintrevimab in the U.S., we intend to seek an APA and to sell product directly to wholesalers and/or distributors while our request for an APA is pending.

Addressable Patient Populations

Pre-Exposure Prophylaxis (PrEP)

In an EUA environment, the Healthcare Provider and Patient Fact Sheets specify the patient populations eligible to receive COVID-19 treatment and prevention, and utilization of PrEP products is bound by these specifications. If we are successful with our request for EUA of adintrevimab for pre-exposure prophylaxis, we estimate that the total addressable PrEP market for adintrevimab in the U.S. is approximately 7-8 million immunocompromised patients.

For example, the tixagevimab/cilgavimab February 2022 Fact Sheet states, in part, that tixagevimab/cilgavimab may only be used in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2; and
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination; or
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

CDC Guidelines suggest prioritizing the following patient populations due to limited drug supply:

- Patients who are within 1 year of receiving B-cell depleting therapies (e.g., rituximab, ocrelizumab, ofatumumab, alemtuzumab);
- Patients receiving Bruton tyrosine kinase inhibitors;
- Chimeric antigen receptor T cell recipients;
- Post-hematopoietic cell transplant recipients who have chronic graft versus host disease or who are taking immunosuppressive medications for another indication;
- Patients with hematologic malignancies who are on active therapy;
- Lung transplant recipients;
- Patients who are within 1 year of receiving a solid-organ transplant (other than lung transplant);
- Solid-organ transplant recipients with recent treatment for acute rejection with T or B cell depleting agents;
- Patients with severe combined immunodeficiencies; and
- Patients with untreated HIV who have a CD4 T lymphocyte cell count <50 cells/mm3.

If we are successful with our request for emergency use authorization of adintrevimab for pre-exposure prophylaxis, Adagio estimates that the total addressable PrEP market for adintrevimab in the U.S. is approximately 7-8 million immunocompromised patients.

We have conducted several waves of market research with physicians that have reflected that there are gaps in pre-exposure prophylactic alternatives in a variety of U.S. populations. Specifically, Adagio recently commissioned a consulting firm to conduct epidemiological analyses supplemented with physician interviews to quantify the size of the adult immunocompromised population in the United States. Their analysis suggested that there are an additional 10-12 million adults in the U.S. with impaired immune responses attributable to conditions such as uncontrolled Type 2 diabetes and autoimmune disorders such as severe multiple sclerosis, psoriasis, rheumatoid arthritis, and irritable bowel disease, bringing the total potential addressable immunocompromised population in the U.S. closer to 20 million patients. Extrapolated to European Union countries (whose population is approximately 1.5x that of the United States), there are an additional 30 million immunocompromised adults that could be candidates for PrEP therapy in the EU.

Additional populations identified include:

- Of the 200 million “fully-vaccinated” adults, the 20% who will “definitely not” not seek a booster (200 million adults x .20 = 40 million adults);
- Of the 200 million “fully-vaccinated” adults, the 1-2% who experienced side effects so severe they would not seek a booster (200 million adults x .015 = 3 million adults);
- The 20% of the unvaccinated adult population (15% of the U.S. population) who refuse to get vaccinated but who have indicated interest in neutralizing monoclonal antibody therapy (258 million adults x .15 x .20 = 7.7 million adults); and
- Of the 48 million children < 12 years old, the approximately 1% who are immunocompromised and/or have health conditions that predispose them to negative outcomes with COVID-19 (48 million children < 12 x .01 = 480,000).

Treatment

In an EUA environment, the Healthcare Provider and Patient Fact Sheets specify the patient populations eligible to receive COVID-19 treatments. These Fact Sheets are largely driven by the CDC’s Guidelines, which are updated frequently.

Specifically, the CDC COVID-19 Treatment Guidelines prioritize the following risk groups for anti-SARS-CoV-2 therapy based on 4 key elements: age, vaccination status, immune status, and clinical risk factors. The groups are listed by tier in descending order of priority:

Tier 1
- Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); or
- Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors)

Tier 2
- Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)

Tier 3
- Vaccinated individuals at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors)

Tier 4
- Vaccinated individuals at risk of severe disease (anyone aged ≥65 years or anyone aged <65 with clinical risk factors)

In 2020, the CDC estimated that 45% of the U.S. adult population, or 115 million individuals, have one or more comorbidities associated with increased risk for complications from SARS-CoV-2 infections.

We have conducted several waves of market research with physicians that have reflected that there are gaps in COVID-19 treatment alternatives in a variety of U.S. patient populations, including:

- Infected patients concerned about “Long COVID” seeking to rapidly drive down their viral load; and
- Infected patients for whom quarantining is not an option due to impending travel, work obligations, or other reasons.

Post-Exposure Prophylaxis (PEP)

In an EUA environment, the Healthcare Provider and Patient Fact Sheets specify the patient populations eligible to receive COVID-19 post-exposure prophylaxis. For example, at the time casirivimab/imdevimab was available for distribution, its Healthcare Provider Fact Sheet stated it was authorized for use in:

- Adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are
  - Not fully vaccinated; or
  - Who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications); and
    - Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease Control and Prevention (CDC); or
    - Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons).

Since exposures are directly related to infections, the size of the PEP population is difficult to quantify at any given time. As a guide, the March 2022 casirivimab/imdevimab Physician Letter references the consideration of use in the following U.S. PEP populations:

- 8 million individuals in long-term care facilities
- 2 million incarcerated individuals
- 7 million immunocompromised adults
- 115 million adults who are at high risk for progression to severe COVID-19

We have conducted several waves of market research with physicians that have reflected that there are gaps in post-exposure prophylactic alternatives in a variety of U.S. patient populations, including:

- Exposed patients concerned about “Long COVID” seeking to rapidly drive down their viral load in case they have COVID; and
- Exposed patients for whom quarantining is not an option due to impending travel, work obligations, or other reasons.

Pediatrics

Although children are at lower risk of developing severe COVID-19 compared to adults, a subset of children experience poor outcomes, including severe acute disease, such as the multisystem inflammatory syndrome, or MIS-C, and long-term sequelae of disease, also known as long COVID. Safe and effective therapies are needed to prevent severe disease and hospitalization in high-risk children as well as complications of COVID-19 such as MIS-C and long COVID. Similarly, although there is a paucity of data regarding the immune response to COVID-19 vaccines in children with moderate to severe immunocompromise, a subset of these children may have suboptimal immune responses to vaccines similar to adults with certain forms of immunocompromise and thus have the potential to benefit from a passive immune approach. Currently, the CDC recommends that children ages 5 to 11 with moderate to severe immunocompromise receive a 3 dose primary series of the Pfizer-BioNTech vaccine and that pre-teens and adolescents with moderate to severe immunocompromise receive a total of 4 doses of a mRNA COVID-19 vaccine.

Adintrevimab Attributes vs. Competitive mAbs

We believe adintrevimab has a unique combination of attributes that positions adintrevimab to be a potentially differentiated mAb for both the prevention and treatment of COVID-19. There are no head-to-head trials between adintrevimab and any product, and therefore no safety or efficacy comparisons can be made.

Reducing Risk of Clinical Resistance. Many SARS-CoV-2 variants of concern and variants of interest likely emerged in response to immune pressure exerted on variable amino acid residues such as K417 and E484, which are targeted by public antibodies commonly induced by natural infection and vaccination. Because most of the mAbs currently in development were isolated from COVID-19 survivors and belong to one of the three classes of public RBD-directed antibodies, many of the clinical-stage mAbs show significant loss of potency against multiple variants of concern. For example, casirivimab, bamlanivimab, etesevimab and regandivimab all show significant loss of *in vitro* neutralizing potency against the Beta (B1.351), Gamma (P.1), Iota (B.1.526), Epsilon (B.1.429), and Omicron (B.1.529) variants, which contain mutations at the key amino acid residues recognized by these antibodies. In contrast, the adintrevimab epitope is not readily targeted by endogenous antibodies, thereby potentially increasing the barrier to circulating viral escape. In support of this notion, adintrevimab demonstrates potent neutralizing activity against many SARS-CoV-2 variants that escape recognition by certain clinical-stage or EUA authorized mAbs, including the Alpha (B.1.1.7), Beta (B1.351), Gamma (P.1) and Delta (B.1.617.2) variants of concern. Adintrevimab also displays neutralizing activity against the Omicron BA.1 sub-variant, albeit with reduced potency relative to earlier variants, and no activity against the BA.2 sub-variant.

Half-Life Extension. Adintrevimab was engineered from its parent antibody, ADG2, with a modification in the Fc region that results in enhanced binding to FcRn at low pH levels. Enhanced binding to FcRn receptors at low pH levels improves FcRn-mediated antibody recycling, leading to an extended serum half-life in humans. The prolonged half-life for adintrevimab is supported by preliminary pharmacokinetic data from the Phase 1 healthy volunteer study. Adintrevimab has the potential to provide durable protection by virtue of its potency and half-life extension, depending on the variant.

Effector Function. Antibodies with Fc-mediated immune effector function summon immune cells and other immune mediators to the site of infection to help destroy infected cells and clear the infection. Preclinical *in vivo* studies for other SARS-CoV-2 mAbs also suggest that Fc effector functions help to modulate protective immune responses. Notably, tixagevimab/cilgavimab includes Fc modifications that reduce innate immune effector functions. In contrast, adintrevimab was engineered to retain Fc-mediated innate immune effector activity, including ADCC and ADCP.

Potency. Adintrevimab displays highly potent neutralizing activity (defined as *in vitro* IC_{50} approximately equal to 0.01 mcg/mL or less) against the majority of variants of concern and variants of interest, including Alpha (B.1.1.7), Beta (B1.351), Gamma (P.1) and Delta (B.1.617.2). Adintrevimab also demonstrates neutralizing activity against the Omicron BA.1 and BA.1.1 variants with *in vitro* IC_{50}s of approximately 1.0 mcg/mL. Adintrevimab did not show detectable neutralizing activity against the BA.2 variant in authentic virus neutralization assays. Importantly, when combining the overall neutralization breadth, including additional SARS-like viruses, and potency profile, adintrevimab is potentially differentiated from almost all clinical-stage and EUA authorized SARS-CoV-2-specific antibodies.

Convenient Dosing Regimen. Intravenous administration of currently available COVID-19 mAbs requires specialized facilities that are properly equipped to accommodate IV dosing in actively infected patients, which may lead to a delay in administration. Given the potency, low viscosity and high concentration formulation of adintrevimab, we are developing adintrevimab as an IM injection for both the prevention and treatment of COVID-19.

Breadth. Adintrevimab has demonstrated broad neutralizing activity against most SARS-CoV-2 variants and other SARS-like viruses that infect human cells through the same hACE2 receptor pathway as SARS-CoV-2. To our knowledge, the only other mAb in late-stage clinical development that has demonstrated activity against additional SARS-like viruses is sotrovimab, but with lower potency against most variants compared to adintrevimab.

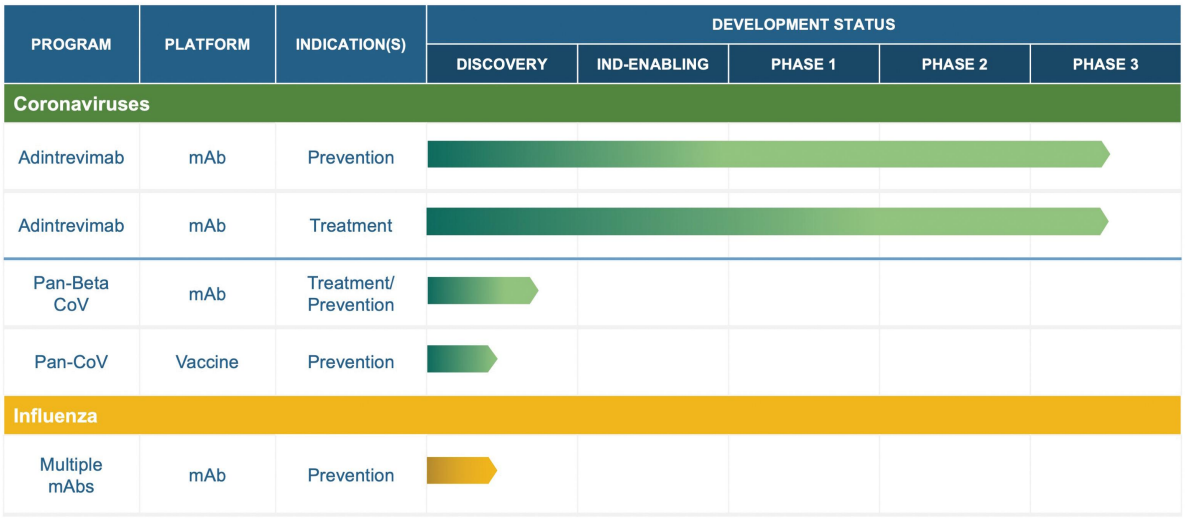
Adintrevimab Attributes vs. Antivirals

We believe adintrevimab has the potential to address certain limitations of currently available COVID antivirals for the treatment of COVID-19, including inconvenient administration and potential for lack of compliance, drug-drug interactions and restrictions of use in certain patient populations. Oral and IV antivirals require patients to take doses over several days, whereas adintrevimab has the potential to provide clinical benefit with a single dose. Oral antivirals require the patient to receive, fill and pay for the prescription via a retail or specialty pharmacy, whereas adintrevimab is expected to be administered in a physician's office or urgent care setting, minimizing delays in administration of therapy. As a mAb, adintrevimab has low potential for drug-drug interactions and pharmacokinetics are not anticipated to be impacted by patient factors such as renal or hepatic impairment. There are no head-to-head trials between adintrevimab and any product, and therefore no safety or efficacy comparisons can be made.

Go-to-Market Strategy

We believe the commercialization of adintrevimab, if authorized or approved, will involve direct sales to governments, including relevant health agencies and national health systems, and in the United States, health insurers, integrated delivery networks and large employers. We intend to establish our own commercial organization in the United States, where we believe a focused commercial infrastructure will be able to successfully commercialize adintrevimab under a regulatory authorization and/or approval, and we are considering commercial options in Europe and beyond. We have begun discussions with some of these entities and will continue to do so as we progress adintrevimab through a potential EUA and commercialization. In certain markets, such as Latin America, Asia-Pacific, including China, and Middle Eastern and African countries, we intend to commercialize adintrevimab through partnerships.

Additional Product Candidates Beyond Adintrevimab



As illustrated in the graphic above, we are developing additional product candidates that target conserved epitopes both within and outside of the RBD for the prevention and treatment of COVID-19 and have initiated discovery programs focused

on preventative agents for additional coronaviruses as well as seasonal and pandemic influenza, which are discussed in greater detail below. We have discontinued development of ADG10 due its less favorable neutralization profile compared to adintrevimab.

Additional Programs in Discovery

We envision additional product development opportunities emerging from our coronavirus discovery efforts for the prevention and treatment of COVID-19. We believe the discovery of additional broadly neutralizing antibodies that target new viral epitopes both within and outside the RBD will ensure long-lasting product activity for COVID-19 as new variants of SARS-CoV-2 arise as well as for future outbreaks of disease that may emerge from additional SARS-like viruses with pandemic potential.

We believe that the robust antibody discovery, engineering, and development capabilities that have enabled our expedited advancement of adintrevimab into clinical trials may also be used to develop preventative or therapeutic options for other infectious diseases, such as seasonal and pandemic influenza. Broadly neutralizing antibodies with extended half-life have the potential to be used directly for the prevention of infection and disease. We have formulated a strategy to discover and engineer potent, broadly neutralizing antibodies targeting certain regions of the influenza virus surface protein, with the goal of generating product candidates with the potential to provide protection against both seasonal and pandemic influenza.

In addition, the epitopes targeted by broadly neutralizing antibodies can be used as templates for the rational design of vaccine immunogens that elicit similar types of antibodies. In collaboration with an academic partner, we have initiated work on the design of coronavirus vaccine antigens that focus the antibody response on highly conserved epitopes defined by adintrevimab and other broadly neutralizing antibodies discovered by us and others.

Manufacturing Strategy

We do not currently own or operate any manufacturing facilities and have invested significant resources to develop a commercial scale manufacturing process for adintrevimab in partnership with our contract manufacturer partner, WuXi, with whom we have been working since our inception. With WuXi, we have manufactured drug substance supply at commercial scale in the planned commercial launch facility. Adintrevimab drug substance is produced using an industry standard mAb manufacturing process including a recombinant Chinese Hamster Ovary, or CHO, commercial cell line, fed-batch suspension cell culture and a chromatography column-based purification process. We have also manufactured drug product supply at commercial scale in the planned commercial launch facility at WuXi. The drug product manufacture uses an industry standard sterile liquid drug product manufacturing process and formulation that enables IM delivery of adintrevimab.

We have established long-term master services agreements with WuXi, pursuant to which we purchase adintrevimab drug substance and drug product for both clinical and commercial supply. The master services agreements are also applicable to any future clinical candidates identified for development, should we elect to use WuXi for development and supply of those candidates. We may stop placing orders under the master services agreements at any time, provided that we fulfill our obligations to make payment for, or pay cancellation-related costs related to, all committed purchases. Either party may also terminate the master services agreements with respect to an uncured breach by the other party in accordance with the terms of the agreements. The agreements include confidentiality and intellectual property provisions to protect our proprietary rights related to our product candidates.

We have also established a cell line license agreement with WuXi that allows for the transfer and use of the commercial cell line currently used in the manufacture of adintrevimab drug substance at WuXi. This license enables cell line and manufacturing process transfer to additional contract manufacturers. We are obligated to pay WuXi royalties in the range of 0.3% to 0.5% based on our net sales of any products covered by the cell line license agreement, unless we use WuXi to manufacture all of our commercial supplies, and we may buy out our royalty obligations by making a one-time payment of $15.0 million to WuXi at our option. Royalties are due on a licensed product-by-licensed product basis commencing on the date of the first commercial sale of the applicable product and continue for so long as we commercialize licensed products or until we exercise our option to buy out the royalty obligations.

We expect to continue to devote significant resources to the manufacture of adintrevimab, and we do not expect any meaningful impediments to executing our current supply plan to provide under EUA or for commercial use. However, within the context of the global pandemic, sufficient capacity for commercial scale manufacturing has been constrained on a worldwide basis. While any reduction or halt in the supply of adintrevimab drug substance or drug product could limit our ability to supply product until a replacement contract manufacturer is found and qualified, we believe that we have sufficient

supply of adintrevimab to support our clinical trial needs and to fulfill our initial supply needs upon receipt of an EUA or BLA approval, if granted. We will also continue to apply mitigation strategies to ensure minimal disruption to our manufacturing supply due to global raw material supply chain shortages. We continue to identify additional drug substance and drug product contract manufacturers to ensure that we will have sufficient capacity and redundancy within our supply chain to avoid product shortages or product delays in the future, This continued surveillance of drug substance and drug product contract manufacturer capabilities applies to our adintrevimab program as well as to our clinical pipeline candidates.

Our Relationship with Adimab

We were founded in June 2020 by Adimab to focus initially on the development of antibodies for both the prevention and treatment of COVID-19. Adimab is a leading provider of antibody discovery, engineering and optimization services and has established an extensive presence in the drug discovery industry.

We are party to an assignment and license agreement with Adimab under which Adimab assigned to us its rights to all existing coronavirus antibodies controlled by it and their derivatives, including adintrevimab. See "—Licensing, Collaborations and Partnerships—Assignment and License Agreement with Adimab." In addition, in May 2021, we entered into a funded discovery agreement with Adimab focused on discovery efforts for new antibodies that may be effective against other coronaviruses and influenza, both of which have the potential to cause pandemics. In the event that Adimab discovers an antibody that is expected to meet certain product profiles developed by Adagio, Adagio will have the exclusive option to require Adimab to assign us its rights in any such antibody and to grant us certain licenses. See "—Licensing, Collaborations and Partnerships—Collaboration Agreement with Adimab."

Licensing, Collaborations and Partnerships

Adimab Assignment Agreement

In July 2020, we entered into an assignment and license agreement with Adimab, or the Adimab Assignment Agreement, with respect to discovery and optimization of coronavirus-specific antibodies, including COVID-19 and SARS. Under the Adimab Assignment Agreement, Adimab assigned to us its rights to all existing coronavirus antibodies controlled by it and their derivatives, patents claiming such antibodies, know-how related to such antibodies, and biological and chemical materials specifically related to such antibodies. Adimab also granted us a non-exclusive, worldwide, royalty-bearing, sublicensable license to certain of its antibody discovery and optimization platform technology to research, develop, make, use, and sell coronavirus antibodies and products containing or comprising coronavirus antibodies, provided that we may not use such licensed rights to discover or optimize antibodies. Adimab cannot grant any third party any license or right under any patent claiming our coronavirus antibodies and cannot deliver our coronavirus antibodies to third parties; however, we have limited recourse in the event of accidental disclosures.

We are obligated to use commercially reasonable efforts to achieve specified development and regulatory milestones for products in certain major markets and to commercialize a product in any country in which we obtain marketing approval. We are obligated to pay Adimab quarterly for its services performed under the agreement at a specified full-time equivalent rate.

In July 2020, in consideration for the rights assigned and license conveyed under the Adimab Assignment Agreement, we issued 5,000,000 shares of our Series A preferred stock, then having a fair value of $40.0 million, to Adimab. In addition, under the Adimab Assignment Agreement, we are obligated to pay Adimab up to $24.6 million upon the achievement of specified development and regulatory milestones for the first two products that comprise or contain coronavirus antibodies assigned to us, antibodies discovered or optimized under the Adimab Assignment Agreement, or any derivative of such antibody, or the Products. Through December 31, 2021, we had made aggregate milestone payments of $7.5 million to Adimab under the Adimab Assignment Agreement. We are also obligated to pay Adimab royalties of a mid single-digit percentage based on annual aggregate worldwide net sales of any Products, subject to reductions for third-party licenses, biosimilar competition, compulsory licensing and a royalty floor. The royalty term expires for each Product on a country-by-country basis beginning upon the first commercial sale of each Product and ending on the later of (i) 12 years after the first commercial sale of such Product in such country and (ii) the expiration of the last valid claim of any patent in such country that was assigned to us under the Adimab Assignment Agreement or that claims priority to any such patent. If we commercialize any products as a diagnostic device (other than a companion diagnostic device) or as a research reagent, we must negotiate reasonable financial terms for such products.

The Adimab Assignment Agreement will expire, unless earlier terminated, on the expiration of the last-to-expire royalty term. We have the right to terminate the Adimab Assignment Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either we or Adimab may terminate the Adimab Assignment Agreement if the other

party commits a material breach of the agreement and fails to cure such breach within a specified cure period after written notice is provided, except that after the initiation of the first clinical trial of a Product, Adimab may only terminate the agreement if we materially breach, and do not cure, our diligence obligation or a payment obligation. Upon expiration of the Adimab Assignment Agreement, the license becomes royalty-free, irrevocable and perpetual. Upon termination of the Adimab Assignment Agreement, all licenses and rights granted by either party will terminate and, in the case of our termination for convenience or Adimab's termination for our material breach, we are required to assign to Adimab all right, title and interest to the patents assigned by Adimab to us or that claim priority to such patents.

Through December 31, 2021, we had made aggregate payments of $9.0 million to Adimab under the Adimab Assignment Agreement, inclusive of the milestone payments.

Adimab Collaboration Agreement

In May 2021, we entered into a collaboration agreement with Adimab, or the Adimab Collaboration Agreement, for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Collaboration Agreement, we and Adimab will collaborate on research programs for a specified number of targets selected by us within a specified time period. If Adimab is unable to generate antibodies directed against a target selected by us, then we may replace such target. Under the Adimab Collaboration Agreement, Adimab granted us a worldwide, non-exclusive license to certain of Adimab's platform patents and technology and antibody patents to perform our responsibilities during the ongoing research period and for a specified evaluation period thereafter, or the Evaluation Term. We granted Adimab a non-exclusive, non-sublicensable license to certain of our patents and intellectual property solely to perform Adimab's responsibilities under the research plans. Under the agreement, we have an exclusive option on a program-by-program basis to obtain licenses and assignments to commercialize selected products containing or comprising antibodies directed against the applicable target, which option may be exercised upon the payment of a specified option fee for each program. Upon exercise of an option, Adimab will assign to us all right, title and interest in the antibodies of the optioned research program and will grant us a worldwide, royalty-free, fully paid-up, non-exclusive, sublicensable license under the Adimab platform technology to research, develop, make, use, and sell the antibodies for which we have exercised our options and products containing or comprising those antibodies.

Under the Adimab Collaboration Agreement, we are obligated to use commercially reasonable efforts to develop, seek marketing approval for, and commercialize one product that contains an antibody discovered in each research program for which we exercise our option to obtain licenses and assignments.

Under the agreement, we are obligated to pay Adimab a quarterly fee of $1.3 million in exchange for Adimab and its affiliates agreeing not to assist in the discovery or optimization of or to direct certain third parties to discover or optimize antibodies that are intended to bind to coronaviruses or influenza viruses, which obligation may be cancelled at our option at any time. For so long as we are paying such quarterly fee (or earlier (i) if we experience a change of control after the third anniversary of the Adimab Collaboration Agreement or (ii) Adimab owns less than a specified percentage of our equity), Adimab and its affiliates will not assist or direct certain third parties to discover or optimize antibodies that are intended to bind to coronaviruses or influenza viruses with limited exception. We may also elect to decrease the scope of Adimab's exclusivity obligations and obtain a corresponding decrease in the quarterly fee. For each agreed upon research program that is commenced, we are obligated to pay Adimab quarterly for its services performed during a given research program at a specified full-time equivalent rate; a discovery delivery fee of $0.2 million; and an optimization completion fee of $0.2 million. For each option exercised by us to commercialize a specific research program, we are obligated to pay Adimab an exercise fee of $1.0 million.

We are obligated to pay Adimab up to $18.0 million upon the achievement of specified development and regulatory milestones for each product under the agreement that achieves such milestones. We are also obligated to pay Adimab royalties of a mid single-digit percentage based on annual aggregate worldwide net sales of products, subject to reductions for third-party licenses. The royalty term will expire for each product on a country-by-country basis on the later of (i) 12 years after the first commercial sale of such product in such country and (ii) the expiration of the last valid claim of any patent claiming composition of matter or method of making or using any antibody identified or optimized under the Adimab Collaboration Agreement in such country.

In addition, we are obligated to pay Adimab for Adimab's performance of certain validation work with respect to certain antigens acquired from a third party. In consideration for this work, we are obligated to pay Adimab royalties of a low single-digit percentage based on annual aggregate worldwide net sales of products that contain such antigens for the same royalty term as antibody-based products, but we are not obligated to make any milestone payments for such antigen products.

The Adimab Collaboration Agreement will expire (i) if we do not exercise any option, upon the conclusion of the last Evaluation Term for the research programs, or (ii) if we exercise an option, on the expiration of the last royalty term for a product in a particular country, unless the agreement is earlier terminated. We may terminate the Adimab Collaboration Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either party may terminate the Adimab Collaboration Agreement in the event of a material breach by the other party that is not cured within specified cure periods. Following termination, we are prohibited from (i) researching, developing, manufacturing or commercializing, any products containing antibodies discovered under the agreement, (ii) practicing, licensing, assigning, granting options to, or otherwise covenanting away rights to the foregoing products, and (iii) licensing or otherwise granting covenants not to sue third parties for the foregoing products.

Through December 31, 2021, we had made aggregate payments of $2.6 million to Adimab under the Adimab Collaboration Agreement.

Research Collaboration and License Agreement with The Scripps Research Institute

In August 2021, we entered into a research collaboration and license agreement, or the Research Agreement, with The Scripps Research Institute, or TSRI. Under the terms of the Research Agreement, TSRI will perform research activities to identify vaccine candidates for the prevention, diagnosis or treatment of influenza or beta coronaviruses, or the Research Program, which is expected to be completed by August 2023. As of December 31, 2021, we had paid TSRI an aggregate of $1.5 million in funding, which is credited against research funding payable by the Company under the Research Agreement. Additionally, we are obligated to make specified payments to TSRI to the extent that TSRI complies with certain exclusivity covenants.

Pursuant to the terms of the Research Agreement, we were granted an exclusive option to acquire an exclusive, worldwide, sublicensable license under TSRI's rights in certain patent rights and know-how for the exploitation of any vaccine product containing, comprised of, or derived from, any vaccine candidate identified or developed under the Research Agreement, subject to certain exceptions, conditions and reserved rights. As of December 31, 2021, we have not exercised this option.

To the extent any licensed product covered by the Research Agreement is commercialized, the Company is obligated to pay TSRI royalties of a low single-digit percentage on a product-by-product and country-by-country basis based on a percentage of net sales, subject to reduction and floor. Royalties are payable for each product on a country-by-country basis through the later of (i) the expiration of the last valid claim of any patent covering such product in such country or (ii) 12 years from the first commercial sale of such product. The Research Agreement will expire when no further royalties are due to TSRI.

Cell Line License Agreement with WuXi

We are also party to a Cell Line License Agreement with WuXi, entered into as of December 2, 2020. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments" and "—Manufacturing Strategy."

License Agreement with Biocon Biologics Limited

In July 2021, we entered into a license agreement with Biocon to combat the ongoing COVID-19 crisis in southern Asia. Under the license agreement, we granted Biocon exclusive rights to manufacture and commercialize an antibody treatment in India and additional select emerging markets based on the commercial process developed for adintrevimab. As part of the agreement, Biocon will be granted access to the data from our ongoing Phase 2/3 adintrevimab clinical trials and access to our anticipated EUA package, as well as regulatory submissions, to support approval or emergency authorization in India and other select emerging markets.

Competition

The biotechnology and pharmaceutical industry is characterized by the rapid evolution of technologies and understanding of disease etiology, intense competition and a strong emphasis on intellectual property. We believe that our approach, strategy, scientific, development and manufacturing capabilities, know-how, partnerships and experience provide us with competitive advantages. However, we expect substantial competition from multiple sources, including major pharmaceutical, specialty pharmaceutical and existing or emerging biotechnology companies, academic research institutions, governmental agencies and public and private research institutions worldwide. Many of our competitors, either alone or through collaborations, have

significantly greater financial resources and expertise in research and development, preclinical testing, conducting clinical trials, manufacturing, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These entities also compete with us in recruiting and retaining qualified scientific, clinical, manufacturing and management personnel, establishing clinical trial sites and enrolling patient in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do.

We face competition from segments of the pharmaceutical, biotechnology and other related markets that pursue the development of antibody and small molecule antivirals targeting COVID-19. Companies that have authorized or late-stage COVID-19 antibody-based programs include AstraZeneca plc, Brii Biosciences Limited, Celltrion Healthcare Co, Ltd., Eli Lilly and Co, Regeneron Pharmaceuticals, Inc. in collaboration with Roche Pharmaceuticals, SAB Biotherapeutics, Inc. and Vir Biotechnology, Inc. in collaboration with GlaxoSmithKline. In addition, companies that have approved or authorized antiviral programs for the treatment of COVID-19 include Merck and Co., Inc. (oral), Pfizer Pharmaceuticals (oral), and Gilead (IV). Beyond antibody and small molecule antiviral treatments, we also face competition from SARS-CoV-2 vaccines that are either available under EUA, approved or in development for the prevention of COVID-19.

We could see a reduction or elimination in our commercial opportunity if our competitors develop and commercialize drugs that are safer, better tolerated, more effective, more convenient to administer, less expensive, more resistant to viral escape, or receive a more favorable label than our product candidates. Some of our competitors have already obtained EUAs from the FDA for the treatment of mild to moderate COVID-19 in high risk patients and the prevention of COVID-19 in immunocompromised patients, and others in the future may obtain FDA or other regulatory approval or authorization more rapidly than we may, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price and the availability of reimbursement from government and other third-party payors.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain patent and other proprietary protection in the United States and in other countries for commercially important technology, current and future inventions, improvements and know-how related to our business; defend and enforce our patents and other intellectual property; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating or otherwise violating the valid enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, selling, offering to sell or importing our products may depend on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. With respect to both licensed and company-owned intellectual property, we cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our commercial products and methods of manufacturing the same. Our pending PCT patent applications are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. Furthermore, our pending U.S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional U.S. patent application within one year of filing of the U.S. provisional patent application with the USPTO. If we do not timely file any national stage patent applications or non-provisional U.S. patent applications, we may lose our priority date with respect to our PCT and provisional U.S. patent applications and any patent protection on the inventions disclosed in such patent applications. See “Risk Factors—Risks Related to Our Intellectual Property.”

We actively seek to protect our proprietary technology, inventions and other intellectual property that is commercially important to the development of our business by a variety of means, such as seeking, maintaining, and defending patent rights, whether developed internally or licensed from third parties. We also may rely on trade secrets and know-how relating to our proprietary technology platform, on continuing technological innovation and on in-licensing opportunities to develop, strengthen and maintain the strength of our position in the antibody field that may be important for the development of our business. We also intend to seek patent protection or rely upon trade secret rights to protect other technologies that may be used to discover and validate targets, as well as to manufacture and develop novel antibody products. Additional regulatory protection may also be afforded through data exclusivity, market exclusivity and patent term extensions where available.

We file patent applications directed to compositions comprising our antibodies, classes of antibodies covering our product candidates, use of such antibodies for preventing and treating disease, diagnostic methods, pharmaceutical compositions, combination therapies, and methods of manufacturing. We continue to review new inventions for patent filings.

Adintrevimab and ADG10

As of March 30, 2022, we own one patent family for which we have one PCT patent application (WO2021/207597, published October 14, 2021), two issued U.S. patents (U.S. 11,192,940, issued December 7, 2021 and U.S. 11,220,536, issued January 11, 2022), one allowed U.S. patent application (U.S. Publication 2021/0388067, published December 16, 2021), one pending U.S. non-provisional patent application, and two foreign patent applications in Argentina and Taiwan. This patent family is directed to broadly neutralizing anti-coronavirus antibodies, including ADG20 (adintrevimab) and ADG10, and uses thereof. These patents and patent applications and any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon such applications, if issued, are expected to expire in 2041, without taking into account any possible patent term adjustment or extension.

As of March 30, 2022, we own a second patent family for which we have filed one PCT patent application and two foreign patent applications in Argentina and Taiwan. This patent family is directed to additional broadly neutralizing anti-coronavirus antibodies, combination therapies, and uses thereof. These patent applications and any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon such applications, if issued, are expected to expire in 2042, without taking into account any possible patent term adjustment or extension.

As of March 30, 2022, we own four additional patent families for which we have filed provisional U.S. patent applications. The first patent family is directed to methods of treating and preventing disease based on data obtained from adintrevimab clinical trials and includes eighteen U.S. provisional patent applications. The second patent family is directed to adintrevimab formulations, combination therapies, and uses thereof and includes one U.S. provisional patent application. The third patent family is directed to additional broadly neutralizing anti-coronavirus antibodies, combination therapies, and uses thereof and includes two U.S. provisional patent applications. Any U.S. non-provisional patent applications timely filed based upon these U.S. provisional patent applications, if issued, are expected to expire in 2042, without taking into account any possible patent term adjustment or extension. The fourth patent family is directed to methods of treating or preventing coronavirus infection using anti-coronavirus antibodies, and any U.S. non-provisional patent applications timely filed based on this U.S. provisional patent application, if issued, is expected to expire in 2043, without taking into account any possible patent term adjustment or extension.

Trade Secrets and Proprietary Information

We also rely, in some circumstances, on trade secrets to protect our technology, including our proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. We seek to protect our proprietary information, data and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. Although these agreements are designed to protect our proprietary information, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Although we generally require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed with all third parties who may have helped to develop our intellectual property or who had access to our proprietary information, or that our agreements will not be breached. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property."

Government Regulation

In the United States, biologic products are licensed by the FDA for marketing under the Public Health Service Act, or the PHS Act, and regulated under the Federal Food, Drug, and Cosmetic Act, or the FDCA. Both the FDCA and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, purity, potency, efficacy, labeling, packaging, storage, record keeping, distribution, marketing, sales, import, export, reporting, advertising and other promotional practices involving biologic products. FDA clearance must be obtained before clinical testing of biologic products. FDA licensure also must be obtained before marketing of biologic 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.

U.S. Development Process

The process required by the FDA before a biologic 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;
- preparation of clinical trial material in accordance with Good Manufacturing Practices, or GMPs;
- 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 by an institutional review board, or IRB, reviewing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCPs, and any additional requirements for the protection of human research subjects and their health information to establish the safety, purity, potency and efficacy of the proposed biologic product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, potency, and efficacy from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection prior to BLA approval of the manufacturing facility or facilities where the biologic product is produced to assess compliance with GMPs to assure that the facilities, methods and controls are adequate to preserve the biologic's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical study sites that generated the data in support of the BLA;
- potential FDA Advisory Committee meeting to elicit expert input on critical issues, including a vote by external committee members;
- FDA review and approval, or licensure, of the BLA and payment of associated user fees, when applicable; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

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

The clinical study sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some nonclinical testing typically continues after the IND is submitted. An IND is an exemption from the FDCA that allows an unapproved product to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational product to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA requests certain changes to a protocol before the trial can begin or places the clinical trial on hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biologic product candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials may involve the administration of the biologic product candidate to healthy volunteers or subjects under the supervision of qualified investigators, generally physicians not employed by or under the study sponsor's control. Clinical trials involving some products for certain diseases may begin with testing in patients with the disease. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects or his or her legal representative provide informed consent. Further, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which the clinical trial will be conducted. IRBs are charged with protecting the welfare and

rights of study participants and consider such items as whether the risks to individuals participating in clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Additionally, 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.

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

- ***Phase 1***. The biologic product is initially introduced into healthy human subjects and tested for safety. In the case of some biologic products for rare diseases, the initial human testing is often conducted in patients.
- ***Phase 2***. The biologic product is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the biologic product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- ***Phase 3***. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the biologic product and provide an adequate basis for product labeling. In biologics for rare diseases where patient populations are small and there is an urgent need for treatment, Phase 3 trials might not be required if an adequate risk/benefit can be demonstrated from the Phase 2 trial.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other studies, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor or its 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 biologic has been associated with unexpected serious harm to patients.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the physical characteristics of the biologic as well as finalize a process for manufacturing the product in commercial quantities in accordance with GMP requirements. To help reduce the risk of the introduction of adventitious agents with the use of biologics, the PHS Act emphasizes the importance of manufacturing control for biologic 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.

There are also various laws and regulations regarding laboratory practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances in connection with the research. In each of these areas, the FDA and other regulatory authorities have broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products and withdraw approvals.

Information about certain clinical trials must be submitted within specific timeframes to the NIH for public dissemination on its clinicaltrials.gov website. Sponsors or distributors of investigational products for the diagnosis, monitoring or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

U.S. Review and Approval Processes

After the completion of clinical trials of a biological product, FDA approval of a BLA must be obtained before commercial marketing of the product. 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. The testing and approval processes require substantial time and effort, and there can be no assurance that the FDA will accept the BLA for filing and, even if filed, that any approval will be granted on a timely basis, if at all.

Under the Prescription Drug User Fee Act, as amended, or the PDUFA, each BLA may be accompanied by a significant user fee. Under federal law, the submission of most applications is subject to an application user fee. The sponsor of an approved application is also subject to an annual program fee. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business.

Within 60 days following submission of the application, the FDA reviews the BLA to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing. The application also needs to be published and submitted in an electronic format that can be processed through the FDA's electronic systems. If the electronic submission is not compatible with the FDA's systems, the BLA can be refused for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, potent and effective for its intended use, has an acceptable purity profile and is being manufactured in accordance with GMPs to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel products or products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a REMS is necessary to assure the safe use of the biological product. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA may 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 GMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical trial sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements. To assure GMP and GCP compliance, an applicant must incur significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control.

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

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a risk management plan, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4 clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. As a condition for approval, the FDA may also require additional nonclinical testing as a Phase 4 commitment.

One of the performance goals agreed to by the FDA under the PDUFA is to review and render a decision on standard BLAs within 10 months of filing and priority BLAs within six months of filing. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs, and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or if the BLA sponsor provides additional

information or clarification regarding information already provided in the submission within the three months preceding the PDUFA goal date.

Emergency Use Authorization (EUA)

In emergency situations, such as a pandemic, and with a declaration of a public health emergency by the Secretary of the Department of Health and Human Services, or HHS, the FDA has the authority to allow unapproved medical products or unapproved uses of cleared or approved medical products to be used to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological or nuclear warfare threat agents when there are no adequate, approved and available alternatives.

Under this authority, the FDA may issue an EUA if the following four statutory criteria have been met: (1) a serious or life-threatening condition exists; (2) evidence of effectiveness exists; (3) a risk-benefit analysis shows that the benefits of the product outweigh the risks; and (4) no other alternatives exist for diagnosing, preventing or treating the disease or condition. The "may be effective" standard for EUAs requires a lower level of evidence than the "effectiveness" standard that FDA uses for product clearances or approvals in non-emergency situations. The FDA assesses the potential effectiveness of a possible EUA product on a case-by-case basis using a risk-benefit analysis. In determining whether the known and potential benefits of the product outweigh the known and potential risks, the FDA examines the totality of the scientific evidence to make an overall risk-benefit determination. Such evidence, which could arise from a variety of sources, may include (but is not limited to) results of domestic and foreign clinical trials, *in vivo* efficacy data from animal models, *in vitro* data, as well as the quality and quantity of the available evidence.

Once granted, an EUA will remain in effect and generally terminate on the earlier of (1) the determination by the Secretary of HHS that the public health emergency has ceased or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved. After the EUA is no longer valid, the product is no longer considered to be legally marketed and one of the FDA's non-emergency premarket pathways would be necessary to resume or continue distribution of the subject product.

The FDA also may revise or revoke an EUA if the circumstances justifying its issuance no longer exist, the criteria for its issuance are no longer met, or other circumstances make a revision or revocation appropriate to protect the public health or safety.

On January 31, 2020, the Secretary of HHS issued a declaration of a public health emergency related to COVID-19. On February 4, 2020, HHS determined that COVID-19 represents a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and, subsequently, declared on March 24, 2020 that circumstances exist to justify the authorization of emergency use of certain medical products, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA. The declaration of the Secretary of HHS has been further updated, and the FDA has issued numerous guidances to sponsors seeking to obtain EUAs to diagnose and treat COVID-19.

Post-Approval Requirements

Maintaining substantial compliance with applicable federal, state and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to GMP. We will rely, and expect to 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 GMP regulations, including quality control and quality assurance and maintenance of records and documentation.

Following approval, the manufacturing facilities are subject to biennial inspections by the FDA, and such inspections may result in an issuance of FDA Form 483 deficiency observations, an untitled letter, or a warning letter, which can lead to plant shutdown and other more serious penalties and fines. Prior to the institution of any manufacturing changes, a determination needs to be made whether FDA approval is required in advance. If not done in accordance with FDA expectations, the FDA may restrict supply and may take further action. Annual product reports are required to be submitted annually. Other post-approval requirements applicable to biological products include reporting of GMP deviations that may affect the identity, potency, purity and overall safety of a distributed product, record-keeping requirements, reporting of adverse events, reporting updated safety and efficacy information and complying with electronic record and signature requirements.

After a BLA is approved, the product also may be subject to official lot release. 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. 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, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA may conduct laboratory research related to the regulatory standards on the safety, purity, potency and effectiveness of biological products. Systems need to be put in place to record and evaluate adverse events reported by healthcare providers and patients and to assess product complaints. An increase in severity or new adverse events can result in labeling changes or product recalls. Defects in manufacturing of commercial products can result in product recalls.

We 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 inpatient 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 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 applicable U.S. 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 or license revocation, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect.

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 GMPs and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain GMP 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.

Expedited Review and Approval Programs

The FDA has various programs, including fast track designation, priority review, accelerated approval and breakthrough therapy designation, that are intended to expedite or simplify the process for the development and FDA review of biological products that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new biological products to patients earlier than under standard FDA review procedures. To be eligible for a fast track designation, the FDA must determine, based on the request of a sponsor, that a biological product is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA will determine that a product will fill an unmet medical need if it will provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a fast track BLA before the application is complete, a process known as rolling review.

The FDA may give a priority review designation, such as a rare pediatric disease designation, to biological products that treat a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. A priority review means that the goal for the FDA's review of an application is six months, rather than the standard goal of ten months under current PDUFA guidelines. Most products that are eligible for fast track designation may also be considered appropriate to receive a priority review. In addition, 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 and may be approved on the basis of adequate and well-controlled clinical trials establishing that the biological product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a biological product receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints, and the biological product may be subject to accelerated withdrawal procedures.

Moreover, under the Food and Drug Administration Safety and Innovation Act enacted in 2012, a sponsor can request designation of a product candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug or biological product that 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 the drug or biological product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drug and biological products designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decides that the time period for FDA review or approval will not be shortened. Furthermore, fast track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval and may not ultimately expedite the development or approval process.

Biologics Price Competition and Innovation Act

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, which was enacted as part of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or the ACA, created an abbreviated approval pathway for biological products that are demonstrated to be "biosimilar" or "interchangeable" with an FDA-licensed reference biological product via an approved BLA. Biosimilarity to an approved reference product requires that there be no differences in conditions of use, route of administration, dosage form and strength and no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. Biosimilarity is demonstrated in steps beginning with rigorous analytical studies or "fingerprinting," *in vitro* studies, *in vivo* animal studies and generally at least one clinical study, absent a waiver from the Secretary of the Department of Health and Human Services, or HHS. The biosimilarity exercise tests the hypothesis that the investigational product and the reference product are the same. If at any point in the stepwise biosimilarity process a significant difference is observed, then the products are not biosimilar, and the development of a stand-alone BLA is necessary. In order to meet the higher hurdle of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product, and for a product that is administered more than once, that the risk of switching between the reference product and biosimilar product is not greater than the risk of maintaining the patient on the reference product. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation that are still being evaluated by the FDA. Under the BPCIA, a reference biologic is granted 12 years of exclusivity from the time of first licensure of the reference product.

U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of product candidates, some of a sponsor's 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 Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during the product development and FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period generally is one-half the time between the effective date of an IND and the submission date of a BLA less any time the sponsor did not act with due diligence during the period, plus the time between the submission date of a BLA and the approval of that application less any time the sponsor did not act with due diligence during the period. Only one patent applicable to an approved biological product is eligible for the extension, only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended and the application for the extension must be submitted prior to the expiration of the patent. Moreover, a given patent may only be extended once based on a single product. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Regulation Outside of the United States

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical studies and any commercial sales and distribution 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 studies 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 study application much like the IND prior to the commencement of human clinical studies.

In the European Union, for example, a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with the applicable requirements, clinical study development may proceed. The requirements and process governing the conduct of clinical studies are to a significant extent harmonized at the European Union level but could vary from country to country. In all cases, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. The way clinical trials are conducted in the European Union will undergo a major change when the Clinical Trial Regulation (Regulation (EU) No 536/2014) comes into application, probably in 2022. The Regulation harmonizes the assessment and supervision processes for clinical trials throughout the European Union via a Clinical Trials Information System, which will contain a centralized European Union portal and database.

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. Innovative products that target an unmet medical need may be eligible for a number of expedited development and review programs in the European Union, such as The Priority Medicines, or PRIME, scheme, which provides incentives similar to the breakthrough therapy designation in the United States. Such products are generally eligible for accelerated assessment and may also benefit from different types of fast track approvals, such as a conditional marketing authorization or a marketing authorization under exceptional circumstances granted on the basis of less comprehensive clinical data than normally required (respectively in the likelihood that the sponsor will provide such data within an agreed timeframe or when comprehensive data cannot be obtained even after authorization).

The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic or biosimilar application. 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. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. A Pediatric Investigation Plan, or PIP, in the European Union is aimed at ensuring that the necessary data are obtained to support the authorization of a medicine for children, through studies in children. All applications for marketing authorization for new medicines have to include the results of studies as described in an agreed PIP, unless the medicine is exempt because of a deferral or waiver. This requirement also applies when a marketing-authorization holder wants to add a new indication, pharmaceutical form or route of administration for a medicine that is already authorized and covered by intellectual property rights. Several rewards and incentives for the development of pediatric medicines for children are available in the European Union. Medicines authorized with the results of studies from a PIP included in the product information are eligible for an extension of their supplementary protection certificate by six months, even when the results of the studies are negative. Scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of pediatric medicines. Medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate are eligible for a pediatric-use marketing authorization, which if granted, provides 10 years of market protection.

The United Kingdom left the European Union on January 31, 2020, following which existing EU medicinal product legislation continued to apply in the United Kingdom during the transition period under the terms of the EU-UK Withdrawal Agreement. A transition period, which ended on December 31, 2020, maintained the United Kingdom's access to the EU single market and to the global trade deals negotiated by the European Union on behalf of its members. The transition period provided time for the United Kingdom and European Union to negotiate a framework for partnership for the future, which was crystallized in the Trade and Cooperation Agreement, or TCA, that became effective on January 1, 2021.

As a result of the Northern Ireland Protocol, different rules apply in Northern Ireland than in England, Wales and Scotland, or collectively Great Britain. In general, Northern Ireland continues to follow the EU regulatory regime, but its national medicines and medical devices authority remains the Medicines and Healthcare Products Regulatory Agency, or MHRA. Following the effectiveness of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 on January 31, 2020, the UK regulatory regime for clinical trials, marketing authorizations, importing, exporting and pharmacovigilance largely mirrors that of the European Union.

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 studies, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical studies are 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 or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Pharmaceutical coverage, pricing and reimbursement

Significant uncertainty exits as to obtaining and maintaining coverage and adequate reimbursement for our product candidates, including adintrevimab, and the extent to which patients will be willing to pay out-of-pocket for such products in the absence of reimbursement for all or part of the cost. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government healthcare programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not ensure that other payors will also provide coverage or adequate reimbursement. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate. In addition, 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.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. There may be pricing pressures from third-party payors in connection with the potential sale of any of our product candidates. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and coverage and adequate reimbursement may not be available with respect to the treatments in which our product candidates, if approved, are used under any foreign reimbursement system.

Healthcare Laws and Regulations

Sales of our product candidate, if authorized or approved, or any other future product candidate will be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments in which we might conduct our business. The healthcare laws and regulations that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease of any good, facility, item or service for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value;
- Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs and biologics, that are false or fraudulent;
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors or making any false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their implementing regulations, impose obligations on certain types of individuals and entities regarding the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information;
- The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific 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), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals; and
- The Foreign Corrupt Practices Act, or FCPA, prohibits U.S. businesses and their representatives from offering to pay, paying, promising to pay or authorizing the payment of money or anything of value to a foreign official in order to influence any act or decision of the foreign official in his or her official capacity or to secure any other improper advantage in order to obtain or retain business.

Many states have similar laws and regulations, such as anti-kickback and false claims laws, that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines and state laws that require drug and biologics manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures, as well as state and foreign laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. Additionally, to the extent that any of our products, if approved, are sold in a foreign country, we may be subject to similar foreign laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to significant penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations.

Healthcare Reform

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The United States government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs and biologics. In recent years, Congress has considered reductions in Medicare reimbursement levels for drugs and biologics

administered by physicians. CMS also has authority to revise reimbursement rates and to implement coverage restrictions for some drugs and biologics. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products. While Medicare regulations apply only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors.

The ACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. The ACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. Among other things, the ACA expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs and biologics, expanded the 340B program, and revised the definition of average manufacturer price, or AMP, which could increase the amount of Medicaid drug rebates manufacturers are required to pay to states. The legislation also extended Medicaid drug rebates, previously due only on fee-for-service Medicaid utilization, to include the utilization of Medicaid managed care organizations as well and created an alternative rebate formula for certain new formulations of certain existing products that is intended to increase the amount of rebates due on those drugs. On February 1, 2016, CMS issued final regulations to implement the changes to the Medicaid Drug Rebate program under the ACA. These regulations became effective on April 1, 2016. Since that time, there have been significant efforts to modify or eliminate the ACA. For example, the Tax Cuts and Jobs Act, or the Tax Act, enacted on December 22, 2017, repealed the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, as amended, or the Code, commonly referred to as the individual mandate.

Other legislative changes have been proposed and adopted since passage of the ACA. The Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of an amount greater than $1.2 trillion for the fiscal years 2012 through 2021, triggering the legislation's automatic reductions to several government programs. These reductions included aggregate reductions to Medicare payments to healthcare providers of up to 2.0% per fiscal year, which went into effect in April 2013. Subsequent legislation, including the Infrastructure Investment and Jobs Act, extended the 2% reduction, on average, to 2031 unless additional congressional action is taken. However, pursuant to COVID-19 relief legislation, the 2% Medicare sequester reductions have been suspended from May 1, 2020 through December 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single-source and innovator multiple-source drugs, beginning January 1, 2024. Additionally, on January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, 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.

Further legislative and regulatory changes under the ACA remain possible, although the Biden administration has signaled that it plans to build on the ACA and expand the number of people who are eligible for subsidies under it. President Biden indicated that he intends to use executive orders to undo changes to the ACA made by the Trump administration and would advocate for legislation to expand the ACA. For example, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unknown what form any other such changes or law would take and how or whether it may affect our business in the future. We expect that changes or additions to the ACA or the Medicare and Medicaid programs, changes allowing the federal government to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry.

The ACA has been subject to challenges in the courts. On June 17, 2021, the U.S. Supreme Court dismissed on procedural grounds a challenge that argued that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form, although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future.

It is unclear how such challenges and the healthcare reform measures of the Biden administration will impact the ACA and our business.

The ACA requires pharmaceutical manufacturers of branded prescription drugs and biologics to pay a branded prescription drug fee to the federal government. Each individual pharmaceutical manufacturer pays a prorated share of the branded prescription drug fee, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. Furthermore, the law requires manufacturers to provide a 50% discount off the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap, referred to as the "donut hole." The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans by increasing from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.

The ACA also expanded the Public Health Service's 340B drug pricing program. The 340B drug pricing program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. The ACA expanded the 340B program to include additional types of covered entities: certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, each as defined by the ACA. Because the 340B ceiling price is determined based on AMP and Medicaid drug rebate data, revisions to the Medicaid rebate formula and AMP definition could cause the required 340B discounts to increase. Payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives as well. For example, CMS may develop new payment and delivery models, such as bundled payment models.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent congressional inquiries, executive orders 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, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this rule has been delayed until January 1, 2026. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. As a result of litigation challenging the MFN Model, on December 27, 2021, CMS published a final rule that rescinded the MFN Model interim final rule.

In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to the executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Employees and Human Capital Resources

As of February 1, 2022, we had 101 full-time employees and two part-time employees. Of our 103 full- and part-time employees, approximately 29 have Ph.D. or M.D. degrees and 73 are engaged in research and development activities. We have a remote workforce, with approximately 35% of our employees based in Massachusetts, 12% based in California, 7% based in New Jersey, 7% based in North Carolina, 6% based in Florida, 6% based in Pennsylvania, and the remaining 27% in various additional states, including one in Austria. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

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

Facilities

Since our inception, we have been a virtual company with our employees working from their homes. We rent an office in an office space building in Waltham, Massachusetts for general and administrative purposes. We do not own or lease any laboratory or manufacturing facilities. We believe that our remote working approach is adequate to meet our ongoing needs, and that, if we require physical facilities, we will be able to obtain additional facilities on commercially reasonable terms.

Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10-K and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Summary of Risk Factors

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in this "Risk Factors" section, including the following:

- We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.
- We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.
- We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.
- All of our product candidates are currently in clinical and preclinical development. If we are unable to successfully develop, receive regulatory approval or Emergency Use Authorization, or EUA, for and commercialize our product candidates for the indications we seek, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.
- Because adintrevimab and any future product candidates represent novel approaches to the prevention and treatment of disease, there are many uncertainties regarding the development, market acceptance, third-party reimbursement coverage and commercial potential of our product candidates.
- There can be no assurance that the Public Health Emergency will continue to be in place for an extended period of time and that the product we are developing for COVID-19 would be granted an EUA by the U.S. Food and Drug Administration, or the FDA, or be granted an EUA in the second quarter of 2022 if we submit a request to the FDA for an EUA, or similar authorization by regulatory authorities outside of the United States if we decide to apply for such an authorization. If we do not apply for such an authorization or, if we do apply and no authorization is granted or, once granted, it is terminated, we will be unable to sell our product in the near future and instead, will be required to pursue solely the traditional regulatory approval processes of the FDA and comparable foreign authorities, which are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.
- Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval.
- Lack of awareness or negative public opinion of monoclonal antibody therapies and increased regulatory scrutiny of monoclonal antibody therapies to prevent or treat COVID-19 may adversely impact the development or commercial success of our current and future product candidates.
- We may not be successful in our efforts to build a pipeline of additional product candidates.
- Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.
- Newly emerging and future SARS-CoV-2 variants could reduce the activity and effectiveness of adintrevimab as a potential prevention of or treatment for symptomatic COVID-19.
- Monoclonal antibody therapies are complex and difficult to manufacture. We could experience manufacturing problems or may be unable to access raw materials due to global supply chain shortages, that result in delays in the development or commercialization of our product candidates or otherwise harm our business.

- The affected populations for our lead monoclonal antibody product candidate or our other product candidates may be smaller than we or third parties currently project, which may affect our ability to enroll our clinical trials as well as the addressable markets for our product candidates.
- Adintrevimab and our other monoclonal antibody product candidates may face significant competition from vaccines, antiviral agents and other therapeutics for COVID-19 that are currently available or in development.
- We may experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, or we may pause, delay or terminate enrollment in our clinical trials, which could in turn delay or prevent our receipt of necessary regulatory approvals.
- If we are unable to obtain, maintain and enforce patent protection for our current and future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.
- Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain.
- Certain of our directors, officers and key employees may have actual or potential conflicts of interest because of their positions with Adimab and/or other companies and may not be able to or may choose not to devote sufficient time and attention to our company, or may otherwise have conflicting incentives.
- We previously identified a material weakness in our internal control over financial reporting. We may identify future material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we fail to establish and maintain adequate internal control over financial reporting, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which may adversely affect our business.

Risks Related to our Financial Position and Capital Needs

We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.

Since our inception, we have incurred significant losses, and we expect to continue to incur significant expenses and operating losses for the foreseeable future. Our net losses were $226.8 million for the year ended December 31, 2021 and $65.3 million for the period from June 3, 2020 (inception) to December 31, 2020. As of December 31, 2021, we had an accumulated deficit of $292.1 million. Since our inception, we have financed our operations with net proceeds of $464.7 million raised in our private placements of preferred stock, including the sale of our Series C preferred stock in April 2021, and approximately $327.5 million of net proceeds (after deducting underwriting discounts and offering expenses) from our initial public offering in August 2021. We have no products approved for commercialization and have never generated any revenue from product sales.

All of our product candidates are still in clinical and preclinical testing. We expect to continue to incur significant expenses and operating losses over the next several years. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially as we:

- continue to conduct our ongoing clinical trials of adintrevimab, including advancement through late-stage global clinical trials, as well as initiate and complete additional clinical trials of future product candidates or current product candidates in new indications or patient populations;
- continue to advance the preclinical development of our other product candidates and our preclinical and discovery programs;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- pursue marketing approvals or EUA and reimbursement for our product candidates;
- acquire or in-license other product candidates, intellectual property and/or technologies;
- develop, establish and validate our commercial-scale cGMP manufacturing process;
- manufacture material under current good manufacturing practices, or cGMP, for clinical trials and potential EUA and commercial sales at our contracted manufacturing facilities;

- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;
- establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval or EUA;
- hire and retain additional personnel, including research, clinical, development, manufacturing quality control, quality assurance, regulatory and scientific personnel;
- add operational, financial, corporate development, management information systems and administrative personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

To date, we have not generated any revenue from product sales. To become and remain profitable, we must succeed in developing and eventually commercializing product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, validating manufacturing processes, obtaining regulatory approval or EUA, and manufacturing, marketing and selling any product candidates for which we may obtain regulatory approval or EUA, as well as discovering and developing additional product candidates. All of our product candidates are in clinical or preclinical development. We may never succeed in these activities and, even if we do, may never generate any revenue or revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with product candidate development, we are unable to accurately predict the timing or amount of expenses or when, or if, we will be able to achieve profitability. If we are required by regulatory authorities to perform clinical trials or preclinical studies in addition to those currently expected, or if there are any delays in the initiation and completion of our clinical trials or the development of any of our product candidates, our expenses could increase.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company with a limited operating history. We commenced operations in June 2020, and our operations to date have been largely focused on organizing and staffing our company, business planning, raising capital, acquiring our technology and product candidates, developing our manufacturing capabilities and developing our clinical and preclinical product candidates, including undertaking preclinical studies and conducting clinical trials. To date, we have not yet demonstrated our ability to successfully complete pivotal clinical trials, obtain regulatory approvals or EUA, manufacture a product on a commercial scale, or conduct sales and marketing activities necessary for successful commercialization, and we may not be successful in doing so. Additionally, if we submit a request for an EUA, we may not be successful in receiving an EUA in the second quarter of 2022 or at any time. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will eventually need to transition from a company with a research and clinical focus to a company, if any of our product candidates are approved, capable of supporting commercial activities. We may not be successful in such a transition.

We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Our operations have consumed substantial amounts of cash since inception, and we expect to continue to incur significant expenses and operating losses over the next several years as we continue to develop our product candidate pipeline and build

out our manufacturing capabilities for our product candidates, which, if approved, may not achieve commercial success. Our revenue, if any, will be derived from sales of products that may not be commercially available for a number of years, if at all. If we obtain marketing approval for any product candidates that we develop or otherwise acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. We also expect an increase in our expenses associated with creating additional infrastructure to support operations as a public company. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2021, we had cash, cash equivalents and marketable securities of $591.4 million. As of March 31, 2022, we believe that our existing cash, cash equivalents and marketable securities, will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2024. This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We plan to use our cash, cash equivalents and marketable securities to fund clinical development, manufacturing supply and initial commercialization costs for adintrevimab, and for working capital and other general corporate purposes, including development of additional programs in our pipeline. Our existing cash, cash equivalents and marketable securities may not be sufficient to fund any of our product candidates through regulatory approval. Changes may occur beyond our control that would cause us to consume our available capital before that time, including changes in and progress of our development activities, acquisitions of additional product candidates and changes in regulation. The timing and amount of our funding requirements will depend on many factors, including:

- the rate of progress in the development of adintrevimab and our other product candidates;
- the scope, progress, results and costs of non-clinical studies, preclinical development, laboratory testing and clinical trials for adintrevimab and future product candidates and associated development programs;
- the extent to which we develop, in-license or acquire other product candidates and technologies in our pipeline;
- the scope, progress, results and costs as well as timing of process development and manufacturing scale-up and validation activities associated with adintrevimab and our future product candidates and other programs as we advance them through preclinical and clinical development;
- the number and development requirements of product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the timing and costs of securing sufficient capacity for commercial supply of our product candidates, or the raw material components thereof;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval or EUA;
- the costs necessary to obtain regulatory approvals, if any, for products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the continuation of our existing licensing and collaboration arrangements and entry into new collaborations and licensing arrangements, if at all;
- the need and ability to hire additional research, clinical, development, scientific and manufacturing personnel;
- the costs we incur in maintaining business operations;
- the need to implement additional internal systems and infrastructure;
- the effect of competing technological, product and market developments;

- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs of operating as a public company; and
- the progression of the COVID-19 pandemic and emergence of potential outbreaks of other coronaviruses, including the impact of any business interruptions to our operations or to those of our contract manufacturers, suppliers or other vendors resulting from the COVID-19 pandemic or other similar public health crises.

We will require additional capital to achieve our business objectives. Additional funds may not be available on a timely basis, on favorable terms or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise sufficient additional capital, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

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

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, government or private-party grants, debt financings and license and collaboration agreements. We do not currently have any other committed external source of funds. 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 of such securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred 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 additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. 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 product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Development of our Product Candidates

All of our product candidates are currently in clinical and preclinical development. If we are unable to successfully develop, receive regulatory approval or EUA for and commercialize our product candidates for the indications we seek, or successfully develop any other product candidates, or experience significant delays in doing so, our business will be harmed.

We currently have no products approved for commercial sale, and all of our product candidates are currently in clinical and preclinical development. In February 2021, we initiated a Phase 1 clinical trial evaluating adintrevimab, our lead monoclonal antibody product candidate. We have also advanced adintrevimab into global pivotal trials for the prevention and treatment of COVID-19. We have not previously conducted any later stage or pivotal clinical trials, have limited experience in preparing, submitting and prosecuting regulatory filings and have not previously submitted a biologics license application, or BLA, for any product candidate.

Our ability to generate revenue from our product candidates, which may not occur for several years, if ever, will depend heavily on the successful development, regulatory approval or granting of EUA for the prevention and/or treatment of COVID-19, obtaining of manufacturing supply, capacity and expertise and eventual commercialization of our product candidates. In the absence of a public health emergency, we will not be able to receive an EUA. The success of adintrevimab or any other product candidates that we develop or otherwise may acquire will depend on several factors, including:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- filing acceptable investigational new drug applications, or INDs, with the FDA, or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;

- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials, manufacture the product candidates and complete associated regulatory activities;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing and successfully develop, obtain regulatory approval or EUA for, and then successfully commercialize our product candidates;
- successful enrollment and timely completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- the costs associated with the development of any additional development programs and product candidates we identify in-house or acquire through collaborations;
- receipt of timely marketing approvals from applicable regulatory authorities;
- developing and expanding sales, marketing and distribution capabilities and launching commercial sales of products, if approved, whether alone or in collaboration with others;
- our ability to secure and maintain required state licenses for distribution of our products, if authorized or approved, or other distribution disruptions;
- acceptance of the benefits and use of our products, including method of administration, if approved, by patients, the medical community and third-party payors, for their approved indications;
- the prevalence and severity of adverse events experienced with adintrevimab or any other product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any product candidate that we develop;
- the continuing need for therapies for the prevention and treatment of COVID-19, including due to the continuation and severity of the pandemic, the development of SARS-CoV-2 into an endemic disease or the inability of other available therapies to address COVID-19;
- the continued availability and sufficiency of government funding for the purchase and/or reimbursement of products for the diagnosis, prevention and treatment of COVID-19;
- newly emerging and future SARS-CoV-2 variants could reduce the activity and effectiveness of adintrevimab as a potential prevention of or treatment for symptomatic COVID-19;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trademark and trade secret protection and regulatory exclusivity for our product candidates, if and when approved, and otherwise protecting our rights in our intellectual property portfolio;
- our ability to maintain compliance with regulatory requirements, including Good Clinical Practices, or GCPs, current Good Laboratory Practices, or cGLPs, and cGMPs, and to comply effectively with other rules, regulations and procedures applicable to the development and sale of pharmaceutical products;
- potential significant and changing government regulation, regulatory guidance and requirements and evolving treatment guidelines;
- obtaining and maintaining third-party coverage and adequate reimbursement and patients' willingness to pay out-of-pocket in the absence of such coverage and adequate reimbursement;
- our ability to maintain a continued acceptable safety, tolerability and efficacy profile of the products following approval; and
- the impact of any business interruptions to our operations or those of third parties with which we work, particularly in light of the current COVID-19 pandemic.

If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for any product candidate we develop, we may not be able to continue our operations.

Because adintrevimab and any future product candidates represent novel approaches to the prevention and treatment of disease, there are many uncertainties regarding the development, market acceptance, third-party reimbursement coverage and commercial potential of our product candidates.

COVID-19 is a relatively new disease and the prevention and treatment of this disease is evolving. Another party may be successful in producing a more efficacious prophylaxis or treatment for COVID-19, which may make it more difficult for us to obtain funding or lead to decreased demand for our potential products. Many small and large companies are developing therapies for the prevention and/or treatment of COVID-19, including antibodies, vaccines, antivirals, and other products. Some of these are further along in the development and commercialization process than we are and several of these companies have access to larger pools of capital, including government funding, and broader infrastructure that may make them more successful at developing, manufacturing or commercializing their products globally for the prevention and/or treatment of COVID-19. The success or failure of other companies, or perceived success or failure, may impact our ability to obtain future funding or to successfully commercialize our products for COVID-19 prevention and/or treatment.

Because this is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement and the commercial potential for our product candidates. There can be no assurance as to the length of the clinical trials, the number of patients the FDA or other comparable foreign regulatory authorities will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of antibody products or that the design of or data generated in these trials will be acceptable to the FDA or other comparable foreign regulatory authorities to support EUA, or similar authorization outside of the US, or marketing approval.

In addition, the FDA or other comparable foreign regulatory authorities may take longer than usual to come to a decision on any EUA, BLA or marketing authorization that we submit and may ultimately determine that there is insufficient data, information or experience with our product candidates to support an authorization or approval decision. The FDA or other comparable foreign regulatory authorities may also require that we conduct additional post-marketing studies or implement risk management programs, such as Risk Evaluation and Mitigation Strategies, or REMS, until more experience with our product candidates is obtained. Finally, after increased usage, we may find that our product candidates do not have the intended effect or have unanticipated side effects, potentially jeopardizing initial or continuing regulatory authorization or approval and commercial prospects.

The success of our business depends in part upon our ability to develop engineered monoclonal antibodies that can broadly neutralize SARS-CoV-2, SARS-CoV and additional pre-emergent coronaviruses. We may fail to deliver monoclonal antibodies that are effective in the prevention or treatment of symptomatic COVID-19. Even if we are able to identify and develop such antibodies, we cannot ensure that such product candidates will achieve authorization or marketing approval to safely and effectively prevent or treat symptomatic COVID-19 or other future coronavirus diseases.

If we uncover any previously unknown risks related to our antibodies, or if we experience unanticipated expenses, problems or delays in developing our product candidates, we may be unable to achieve our strategy of building a pipeline of monoclonal antibodies. Further, competitors who are developing products with similar technology may experience problems with their products that could identify problems that would potentially harm our business.

There is no assurance that the approaches offered by our product candidates will gain broad acceptance among doctors or patients or that governmental agencies or third-party medical insurers will be willing to provide reimbursement coverage for our proposed product candidates. Since our current product candidates and any future product candidates will represent novel approaches to treating various conditions, it may be difficult, in any event, to accurately estimate the potential revenues from these product candidates. Accordingly, we may spend significant capital trying to obtain approval for product candidates that have an uncertain commercial market. The market for any products that we successfully develop will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it will cost to commercially manufacture our current product candidates, and the actual cost to manufacture these products could materially and adversely affect the commercial viability of these products. If we do not successfully develop and commercialize products based upon our approach or find suitable and economical sources for materials used in the production of our products, we will not become profitable, which would materially and adversely affect the value of our common stock.

In addition, our monoclonal antibodies may be provided to patients in combination with other agents provided by third parties or by us. The cost of such combination therapy may increase the overall cost of therapy, which may affect our ability to obtain reimbursement coverage for the combination therapy from governmental or private third-party medical insurers.

Preclinical studies and clinical trials are expensive, time-consuming, difficult to design and implement and involve an uncertain outcome. Further, we may encounter substantial delays in completing the development of our product candidates. If we are not able to obtain required regulatory approvals or EUA, we will not be able to commercialize our product candidates, and our ability to generate product revenue will be adversely affected.

All of our product candidates are in clinical and preclinical development and their risk of failure is high. The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because our product candidates are subject to regulation as biological products, we will need to demonstrate that they are safe, pure and potent for use in their target indications. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain and depends upon numerous factors, including the 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 cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Failure can occur at any time during the clinical trial process. Even if our future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our product candidates for their targeted indications or support continued clinical development of such product candidates. Our current or future clinical trial results may not be successful.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA, the European Medicines Agency, or EMA, or other foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. Moreover, results acceptable to support approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA, EMA or other foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional preclinical studies or trials for our product candidates either prior to or post-approval, or they may object to elements of our clinical development program, requiring their alteration.

Of the large number of products in development, only a small percentage successfully complete the FDA's or comparable foreign regulatory authorities' approval processes and are commercialized. Even if we eventually complete clinical testing and receive approval of a new drug application, or NDA, BLA or foreign marketing application for our product candidates, the FDA or the comparable foreign regulatory authorities may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-market clinical trials. The FDA or the comparable foreign regulatory authorities also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or comparable foreign regulatory authorities may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would adversely impact our business and prospects.

Furthermore, even if we obtain regulatory approval for our product candidates, we may still need to develop a commercial organization, establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from commercial and government payors, including government health administration authorities. If we are unable to successfully commercialize our product candidates, we may not be able to generate sufficient revenue to continue our business.

We may experience delays in beginning or conducting clinical trials or numerous unforeseen events before, during or as a result of clinical trials that could delay or prevent our ability to complete clinical trials, receive marketing approval or commercialize our product candidates.

We may experience delays in conducting any clinical trials, and we do not know whether our clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. For example, following our review of data generated in external *in vitro* analyses examining the neutralizing activity of adintrevimab against the Omicron SARS-CoV-2 variant in both authentic and pseudovirus assays, in January 2022 we paused enrollment of new patients in the 300 mg dose arm in both our EVADE and STAMP clinical trials to assess and revise our trial protocols in light of the spread of the Omicron variant. We may experience numerous unforeseen events before, during or after the conduct of our

clinical trials that could delay or prevent our ability to complete such trials or receive marketing approval for or commercialize our product candidates, or that could significantly increase the cost of such trials, including:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching agreement with the FDA, EMA or other regulatory authorities as to the design or implementation of our clinical trials;
- delays in obtaining regulatory authorization to commence a clinical trial;
- challenges in reaching an agreement on acceptable terms with clinical trial sites or prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- delays in obtaining institutional review board, or IRB, approval at each trial site;
- challenges in recruiting suitable patients to participate in a clinical trial;
- challenges in having patients complete a clinical trial or return for post-treatment follow-up;
- inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold;
- clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial;
- failure to perform in accordance with the applicable regulatory requirements, including the FDA's regulations and GCP requirements, or applicable regulatory requirements in other countries;
- addressing patient safety concerns that arise during the course of a trial, including the occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits;
- inability to recruit and/or successfully contract with a sufficient number of clinical trial sites;
- difficulties in manufacturing sufficient quantities of product candidate for use in clinical trials;
- suspensions or terminations by IRBs of the institutions at which such trials are being conducted, by the independent Data Monitoring Committee for such trial or by the FDA or other regulatory authorities due to a number of factors, including those described above;
- changes in regulatory requirements or guidance, or feedback from regulatory authorities that requires us to modify the design or conduct of our clinical trials; for example, in April 2021, the FDA informed us that it had changed its view on allowing high risk patients to be randomized to placebo in the United States in our STAMP treatment trial, which has resulted in modification of the design and conduct of this trial exclusively outside of the United States;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, especially if regulatory bodies require the completion of non-inferiority trials or the sample size needs to be increased based on the outcome rates observed during early trial conduct, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- the screen failure rate for clinical trials of our product candidates may be higher than we anticipate, requiring us to screen larger numbers of patients than originally planned;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have

undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks; for example, we intend to conduct our STAMP treatment trial at sites outside of the United States, and the applicable foreign regulatory authorities may determine that a placebo-controlled trial would expose patients to unacceptable health risks (for example, if alternative effective therapies become available in these regions during the conduct of the trial), which could delay enrollment of our trial and the authorization or approval of adintrevimab;

- the cost of clinical trials of our product candidates may be greater than we anticipate and we may not have funds to cover the costs;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or may not be able to be procured or distributed as needed;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully and timely complete clinical trials of our product candidates or other testing, 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 marketing approval for our product candidates or not obtain marketing approval at all;
- 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 or REMS;
- be subject to additional post-marketing testing requirements;
- be subject to changes in the way the product is administered; or
- have regulatory authorities withdraw or suspend their approval of the product or to impose restrictions on its distribution after obtaining marketing approval.

All of our product candidates will require extensive clinical testing before we are prepared to submit a BLA or marketing authorization application, or MAA, for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for our product candidates and submit a BLA or MAA for regulatory approval of any of our product candidates or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, EMA or other regulatory authorities on our clinical development program, and the FDA, EMA or other regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

We cannot predict with any certainty whether or when we might complete a given clinical trial. If we experience delays in the commencement or completion of our clinical trials, or if we terminate a clinical trial prior to completion, the commercial prospects of our product candidates could be harmed, and our ability to generate revenues from our product candidates may be delayed or lost. In addition, any delays in our clinical trials could increase our costs, slow down the development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and results of operations. In addition, 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.

Russian military action in Ukraine may impact our ability to complete patient follow-up visits in our clinical trials and could cause such clinical trials to be delayed or suspended.

In February 2022, Russia commenced a military invasion of Ukraine. Russia’s invasion and the ensuing response by Ukraine has disrupted and may continue to disrupt our ability to conduct clinical trials in Ukraine and may also impact our

clinical trials activities in the neighboring countries of Moldova and Georgia should Russian military operations expand there. Although the duration, scope and impact of Russia's military action is highly unpredictable, certain data generated at these trial sites might not be able to be validated or assessments may be missed, and our clinical trial sites in Ukraine may suspend or terminate trials and patients could be forced to evacuate or choose to relocate, making them unavailable for further participation in clinical trials and adversely impacting the analysis of the patients enrolled in these trials and the overall safety and efficacy analysis of the trials. Alternative sites to fully and timely compensate for our clinical trial activities in Ukraine may not be available and we may need to find other countries in which to conduct these clinical trials. Furthermore, Russian military action may prevent the FDA from auditing clinical trial sites in Ukraine. Interruptions of clinical trials may delay our clinical development and the potential authorization or approval of our product candidates, which could increase our costs and jeopardize our ability to commence product sales and generate revenues.

There can be no assurance that the Public Health Emergency will continue to be in place for an extended period of time and that the product we are developing for COVID-19 would be granted an EUA by the FDA or similar authorization by regulatory authorities outside of the United States if we decide to apply for such an authorization. If we do not apply for such an authorization or, if we do apply and no authorization is granted or, once granted, it is terminated, we will be unable to sell our product in the near future and instead, will be required to pursue solely the traditional regulatory approval processes of the FDA and comparable foreign authorities, which are lengthy, time consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for our product candidates, our business will be substantially harmed.

We may seek an EUA for the prevention and/or treatment of COVID-19 from the FDA or similar authorization from regulatory authorities outside of the United States, such as conditional marketing authorization from the EMA. If we apply for an EUA and it is granted, an EUA will authorize us to market and sell our COVID-19 monoclonal antibody under certain conditions of authorization as long as the public health emergency exists. The FDA expects that companies that receive an EUA for COVID-19 antibodies will proceed to licensure of their products under a full BLA. The FDA may issue an EUA during a public health emergency if the agency determines that the potential benefits of a product outweigh the potential risks and if other regulatory criteria are met. There is no guarantee that we will apply for an EUA in the second quarter of 2022 or at any time, or other similar authorization or, if we do apply, that we will be able to obtain an EUA or such authorization in the second quarter of 2022 or at any time. If an EUA or other authorization is granted, we will rely on the FDA or other applicable regulatory authority policies and guidance governing products authorized in this manner in connection with the marketing and sale of our product. If these policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of our product could be adversely impacted. An EUA authorizing the marketing and sale of our product will terminate upon expiration of the public health emergency, which is a determination made by the Secretary of the Department of Health and Human Services, or HHS. The FDA may also terminate an EUA if safety issues or other concerns about our product such as loss of neutralizing activity against dominant circulating SARS-CoV-2 variants arise or if we fail to comply with the conditions of authorization. We cannot predict how long the public health emergency will remain in effect. If we apply for an EUA or similar authorization from regulatory authorities outside of the United States, the failure to obtain such authorization or the termination of such an authorization, if obtained, would adversely impact our ability to market and sell our COVID-19 antibody, which could adversely impact our business, financial condition and results of operations. The time required to obtain approval or other marketing authorizations by the FDA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and 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 we may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any drug product candidates in the United States until we receive regulatory approval of a BLA or EUA from the FDA, and we cannot market it in the European Union until we receive approval for a MAA from the EMA, or other required regulatory approval in other countries. To date, we have had discussions with the FDA and have received scientific advice from the Medicines and Healthcare products Regulatory Agency, or MHRA, the Swedish Medical Products Agency, or MPA, the Paul Ehrlich Institute, or PEI, and the European Medicines Agency, or EMA, regarding clinical development programs or regulatory approval for any product candidate within the United States, United Kingdom, Sweden, Germany and European Union, respectively. We have had no discussions with other comparable foreign authorities regarding clinical development programs or regulatory approval for any product candidate outside of these jurisdictions.

Prior to obtaining approval to commercialize any drug product candidate in the United States or abroad, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, EMA or other foreign regulatory agencies, that such product candidates are safe, pure and effective for their intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for

our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- we may be unable to collect sufficient data from clinical trials of our product candidates to support the submission and filing of a BLA with the FDA, MAA with the EMA or other submission;
- we may fail bioresearch monitoring, or BIMO, FDA inspection or comparable foreign regulatory authorities inspection;
- we may fail an FDA or comparable foreign regulatory authorities' inspection of our third-party contract manufacturing or testing facilities for which we contract and test clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may find our contract manufacturing related activities (e.g. process validation, product characterization, product stability and expiry, and comparability establishment) insufficient for approval; and
- the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, the FDA, EMA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Preclinical tests and Phase 1 and Phase 2 clinical trials are primarily designed to test safety, to study pharmacokinetics and pharmacodynamics and to understand the side effects of product candidates at various doses and schedules. Success in preclinical or animal studies and early clinical trials does not ensure that later large-scale efficacy trials will be successful, nor does it predict final results. For example, we may be unable to identify suitable animal disease models for our product candidates, which could delay or frustrate our ability to proceed into clinical trials or obtain marketing approval. Our product candidates may fail to show the desired safety and efficacy in clinical development despite having progressed through preclinical studies and initial clinical trials.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays or rejections as a result of many factors, including changes in regulatory policy during the period of our product candidate development. Any such delays could negatively impact our business, financial condition, results of operations and prospects.

Interim, "top-line" and preliminary results from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, top-line or preliminary results from our clinical trials. Interim results 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. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary, top-line or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line 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.

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 development program, the approvability or commercialization of the particular product candidate or product and our company 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. Any information we determine not to disclose may ultimately be deemed meaningful by you or others 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, product candidates may be harmed, which could significantly harm our business prospects.

Our preclinical studies and clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent, delay or limit the scope of regulatory approval of our product candidates, limit their commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our product candidates.

To obtain the requisite regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved.

We may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and effective for their intended uses. In addition, the FDA or comparable foreign regulatory authorities may determine that antibody monotherapy products are not sufficient and that combination antibody therapies should become the standard of care. The current clinical data available from the STAMP and EVADE trials may be insufficient to support a BLA or marketing authorization and we may not be able to generate additional data if the FDA or comparable foreign regulatory authorities require additional trials in support of a BLA or marketing authorization.

If our product candidates are associated with undesirable effects in preclinical studies or clinical trials or have characteristics that are unexpected, we may decide or be required to perform additional preclinical studies or to halt or delay further clinical development of our product candidates or to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial use for the product candidate, if approved. Some side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from monoclonal antibody therapy targeting an exogenous target, as with our adintrevimab product candidate, can be nonspecific.

If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug, the FDA, EMA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications, or require that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates that we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the product

candidate. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates and may harm our business, financial condition and prospects significantly.

Additionally, if one or more of our product candidates receives marketing approval, and we or others identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or other requirements subject to a REMS;
- we may be required to change the way a product is administered or conduct additional trials;
- we could be sued and held liable for harm caused to patients;
- we may decide to remove the product from the market;
- we may not be able to achieve or maintain third-party payor coverage and adequate reimbursement;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties; and
- our reputation and physician or patient acceptance of our products may suffer.

There can be no assurance that we will resolve any issues related to any product-related adverse events to the satisfaction of the FDA or foreign regulatory agency in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

Lack of awareness or negative public opinion of monoclonal antibody therapies and increased regulatory scrutiny of monoclonal antibody therapies to prevent or treat COVID-19 may adversely impact the development or commercial success of our current and future product candidates.

The clinical and commercial success of our monoclonal antibody therapies will depend in part on public acceptance of the use of monoclonal antibody therapies to prevent of treat COVID-19. Any adverse public attitudes about the use of monoclonal antibody therapies may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients' willingness to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available.

More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for any products once approved. Adverse events in our or others' clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates, all of which would have a negative impact on our business and operations.

We may experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, or we may pause, delay or terminate enrollment of our clinical trials, which could in turn delay or prevent our receipt of necessary regulatory approvals.

Successful and timely completion of clinical trials will require that we enroll, and maintain the enrollment of, a sufficient number of patients. 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 and competition for patients eligible for our clinical trials with competitors that

may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates.

Further, we may determine that enrollment in a clinical trial should be paused, delayed or terminated in order to revise trial protocols in light of preliminary data generated by the trial or new data generated in other studies. For example, following our review of data generated in external *in vitro* analyses examining the neutralizing activity of adintrevimab against the Omicron SARS-CoV-2 variant in both authentic and pseudovirus assays, in January 2022 we paused enrollment of new patients in the 300 mg dose arm in both our EVADE and STAMP clinical trials to assess and revise our trial protocols in light of the global spread of the Omicron variant. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or foreign regulatory authorities. We cannot predict how successful we will be at enrolling patients in future clinical trials. Patient enrollment is affected by other factors, including:

- the severity and difficulty of diagnosing the disease under investigation;
- the contraction of the public health crisis caused by COVID-19;
- the eligibility and exclusion criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the trial protocol, including but not limited to the use of a placebo control or active comparator;
- the perceived risks and benefits of the product candidate in the trial, including relating to monoclonal antibody and/or vaccine approaches;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation;
- the willingness of patients to be enrolled in our clinical trials;
- local, national and/or employer COVID-19 vaccine mandates;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, vaccine mandate policies, travel or quarantine policies that may be implemented, our ability to import and export clinical trial supplies, raw materials and commercial supply and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll, or maintain the enrollment of, a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment pauses or delays in these clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance.

Breakthrough therapy designation by the FDA for any product candidate may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that the product candidate will receive marketing approval.

We may, in the future, apply for breakthrough therapy designation, or the equivalent thereof in foreign jurisdictions (where available), for our product candidates. A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and

the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Product candidates designated as breakthrough therapies by the FDA are also eligible for priority review if supported by clinical data at the time of the submission of the BLA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific indications. As such, we are currently primarily focused on the development of adintrevimab for the prevention and treatment of symptomatic COVID-19. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for these 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 development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate 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 product candidate.

We plan to conduct and may in the future conduct additional clinical trials for our product candidates outside the United States, and the FDA and similar foreign regulatory authorities may not accept data from such trials conducted in locations outside of their jurisdiction.

We are currently conducting, and intend to conduct in the future, clinical trials outside the United States. The acceptance of trial data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions or may not be accepted at all. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence in accordance with GCP standards, and (iii) the data may be considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

We may not be successful in our efforts to build a pipeline of additional product candidates.

We may not be able to continue to identify and develop new product candidates in addition to our current pipeline. Even if we are successful in continuing to build our pipeline, the potential product candidates that we identify may not be suitable for clinical development. For example, product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be successfully developed, much less receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon our approach, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely affect our stock price.

Our business and operations may be adversely affected by the evolving and ongoing COVID-19 global pandemic.

The evolving and constantly changing impact of COVID-19, which was declared a global pandemic by the World Health Organization, or WHO, will directly affect the potential commercial prospects of our lead product candidate for the prevention and treatment of COVID-19. The severity of the global pandemic, the availability, administration and acceptance of vaccines, monoclonal antibodies, antiviral agents and other therapies, potential vaccine mandate policies, and the potential development of "herd immunity" by the global population will affect the design and enrollment of our clinical trials, the potential regulatory authorization or approval of our product candidates and the commercialization of our product candidates, if approved.

In addition, our business and operations may be more broadly adversely affected by the COVID-19 pandemic. The COVID-19 pandemic has resulted in travel and other restrictions in order to reduce the spread of the disease, including public health directives and orders in the United States and the European Union that, among other things and for various periods of time, directed individuals to shelter at their places of residence, directed businesses and governmental agencies to cease non-essential operations at physical locations, prohibited certain non-essential gatherings and events and ordered cessation of non-essential travel. Future remote work policies and similar government orders or other restrictions on the conduct of business operations related to the COVID-19 pandemic may negatively impact productivity and may disrupt our ongoing research and development activities and our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Further, such orders also may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities. Additionally, on September 9, 2021, President Biden issued an executive order obligating parties that contract with the federal government to require their employees to be fully vaccinated against COVID-19, with limited exceptions for certain accommodations, and on November 5, 2021 the Department of Labor's Occupational Safety and Health Administration, or OSHA, issued an emergency temporary standard, or the ETS, requiring all private employers with 100 or more workers to mandate COVID-19 vaccination or produce a weekly test for all employees. Although the executive order has been the subject of legal challenges and is currently enjoined nationwide, there can be no assurance that the executive order will not be upheld and enforced. Further, while the ETS was withdrawn effective January 26, 2022, OSHA has not withdrawn the ETS as a proposed rule. As a company that is likely to have 100 employees at the time such rule may become a final standard, we would be required to mandate COVID-19 vaccination of our workforce or require our unvaccinated employees to be tested weekly if the ETS proposed rule becomes a final standard or if the executive order is upheld in the courts and we were to contract with the federal government. We or our suppliers may incur increased costs, labor disruptions or employee attrition as a result of these mandates. If we or other companies in our supply chain lose employees, it may be difficult in the current competitive labor market to find replacement employees, and this could have a material adverse effect on our business and results of operations.

To date, we have experienced some delays in our development activities as a result of the COVID-19 pandemic. In the future, we anticipate there could be additional or even significant disruptions, delays or uncertainties in our development activities as a result of the COVID-19 pandemic as the outbreak progresses and some of our CROs, CDMOs and other service providers continue to be impacted. In December 2020, shipment of adintrevimab clinical supply by WuXi Biologics (Hong Kong) Limited, or WuXi, was delayed due to the introduction by the Chinese government of a new procedure for the approval of the export of products for the treatment of COVID-19. However, this type of delay is not anticipated to occur in the future, now that this export procedure has been implemented. In addition, we may experience related disruptions in the future that could severely impact our clinical trials, including:

- delays, difficulties or a suspension in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- interruptions in our ability to manufacture and deliver drug supply for trials due to capacity constraints or lack of raw materials;
- interruptions to our ability to supply clinical trial material to clinical trial sites due to supply chain challenges;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- changes in local regulations (including potential vaccine mandates) as part of a response to the COVID-19 outbreak that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- uncertainty around patient enrollment rates due to unpredictable and variable regional rates of infection;

- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA and other regulatory authorities to accept data from clinical trials in these affected geographies.

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, the COVID-19 pandemic may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global COVID-19 pandemic continues to rapidly evolve, particularly with regard to the rapid global spread of the Omicron variant. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence as of the date of this Annual Report, such as the ultimate geographic spread of the disease and the neutralizing activity of adintrevimab and any of our other potential COVID-19 product candidates against the dominant circulating variant(s) at any given time, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business, financial condition and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

The market opportunities for any current or future product candidate we develop, if approved, may be limited to those patients who are ineligible for established therapies or for whom prior therapies have failed, and may be small.

Any revenue we are able to generate in the future from product sales will be dependent, in part, upon the size of the market in the United States and any other jurisdiction for which we gain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved.

The potentially addressable patient population for our current or future product candidates may be limited, if and when approved. Further, even if any of our product candidates are approved by the FDA or comparable foreign regulators, their approved indications may be limited to a subset of the indications that we targeted. Even if we obtain significant market share for any product candidate, if and when approved, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications, including to be used as first- or second-line therapy.

Newly emerging and future SARS-CoV-2 variants could reduce the activity and effectiveness of adintrevimab as a potential prevention of or treatment for symptomatic COVID-19.

Multiple variants of the virus that causes COVID-19 have been documented in the United States and globally during this pandemic, including the highly transmissible Omicron and Delta variants, as well as the regional emergence of the Mu and Lambda variants in South America and the Delta Plus variant in the United Kingdom. Although we have shown in pre-clinical studies that adintrevimab has the potential to broadly neutralize SARS-CoV-2 and the predominantly circulating variants, external *in vitro* analyses to evaluate neutralizing activity of adintrevimab against the Omicron variant generated data showing a greater than 300-fold reduction in neutralizing activity of adintrevimab against the Omicron BA.1 subvariant compared to a reference strain and a lack of neutralizing activity against the Omicron BA.2 subvariant. New SARS-CoV-2 variants could be less impacted by adintrevimab and its mechanism of action, or the results shown in pre-clinical studies may not be replicated in clinical studies. Further, we may not be able to address reductions in neutralization potency with adjustments to the adintrevimab dose or dosing frequency. This would significantly and adversely affect our ability to obtain authorization or approval of and to commercialize adintrevimab. In addition, if our planned dosing of 300 mg of adintrevimab were to be

increased in response to loss of neutralizing activity against dominant circulating SARS-CoV-2 variants or for other reasons, it could impact drug supply and pricing, which could adversely affect our commercial prospects.

We may develop adintrevimab and future product candidates for use in combination with other therapies or third-party product candidates, which exposes us to additional regulatory risks.

We may develop adintrevimab and future product candidates for use in combination with one or more currently authorized or approved therapies to prevent or treat COVID-19, or with therapies that may be authorized or approved in the future. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA, EMA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination antibody therapies appear to be favored by the FDA over monotherapy, and in the future the FDA, EMA and comparable foreign regulatory authorities may determine that monotherapy products should not be approved, eliminating our ability to commercialize adintrevimab as a monotherapy treatment.

We may also evaluate adintrevimab or any future product candidate in combination with one or more other third-party product candidates that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. If so, we will not be able to market and sell adintrevimab or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or comparable foreign regulatory authorities do not approve these other product candidates, or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biologics or antivirals we choose to evaluate in combination with adintrevimab or any product candidate we develop, we may be unable to obtain approval of or market any such product candidate.

The United Kingdom's withdrawal from the European Union may adversely impact our ability to obtain regulatory approvals of our product candidates in the European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the European Union and require us to incur additional expenses in order to develop, manufacture and commercialize our product candidates in the European Union.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to by the United Kingdom and the European Union, as of January 1, 2021, the United Kingdom is no longer subject to the transition period, or the Transition Period, during which European Union rules continued to apply. A trade and cooperation agreement, or the Trade and Cooperation Agreement, that outlines the post-Transition Period trading relationship between the United Kingdom and the European Union was agreed to in December 2020 and was formally entered into on May 1, 2021.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from European Union directives and regulations, Brexit has had, and will continue to have, a material impact on the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom. For example, Great Britain is no longer covered by the centralized procedures for obtaining European Union-wide marketing authorizations from the EMA, and a separate marketing authorization will be required to market our product candidates in Great Britain. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would delay or prevent us from commercializing our product candidates in the United Kingdom or the European Union and limit our ability to generate revenue and achieve and sustain profitability. While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the United Kingdom and the European Union, there are additional non-tariff costs to such trade that did not exist prior to the end of the Transition Period and frequent delays in the transit of goods between the United Kingdom and the European Union. Further, should the United Kingdom diverge from the European Union from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses (when compared to prior to the end of the Transition Period) operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the European Union.

Risks Related to the Manufacturing of our Product Candidates

Monoclonal antibody therapies are complex and difficult to manufacture. We could experience manufacturing problems or may be unable to access raw materials due to global supply chain shortages, that result in delays in the development or commercialization of our product candidates or otherwise harm our business.

The manufacture of monoclonal antibody therapies is technically complex and necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical studies or commercialization efforts.

The manufacturers of pharmaceutical products must comply with strictly enforced cGMP requirements, state and federal regulations, as well as foreign requirements when applicable. Any failure of us or our contract manufacturing organizations to adhere to or document compliance to such regulatory requirements could lead to a delay or interruption in the availability of product for clinical trials or commercial use, or enforcement action from the FDA, EMA or other foreign or state regulatory authorities. If we or our manufacturers were to fail to comply with the FDA, EMA or other foreign or state regulatory authorities, it could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. Our potential future dependence upon others for the manufacture of our product candidates may also adversely affect our future profit margins, if any, and our ability to commercialize any product candidates that receive regulatory approval on a timely and competitive basis.

Biological products are inherently difficult and time-consuming to manufacture. Our program materials are manufactured and tested using technically complex processes and/or methods requiring specialized equipment and facilities and other production constraints, including a number of highly specific raw materials, cell lines and reagents with limited suppliers. Even though we aim to have backup supplies of raw materials, cell lines and reagents whenever possible, we cannot be certain they will be sufficient if our primary sources are unavailable. A shortage of a critical raw material, cell line or reagent, or a technical issue during manufacturing or testing, may lead to an inability to manufacture our product candidate, resulting in delays in clinical development or commercialization plans. Any changes in the manufacturing of components of the raw materials we use could result in unanticipated or unfavorable effects in our manufacturing processes or product quality, resulting in delays.

Any delay, failure or inability to manufacture on a timely basis can impact the timelines for our clinical trials or our commercialization plans. Such delay, failure or inability to manufacture can result from:

- a failure in the manufacturing process itself, for example by an error in manufacturing process, operator or human error, equipment failure, raw material or reagent failure, failure in any step of the manufacturing process, failure to maintain a cGMP environment or failure in quality systems applicable to manufacture (whether by us or our third-party contract development and manufacturing organization), sterility failures, testing failure or contamination during processing;
- a lack of reliability or reproducibility in the manufacturing process itself leading to variability in process execution or in product quality, which may lead to regulatory authorities placing a hold on a clinical trial or commercial supply and distribution or requesting further information on the process, which could in turn result in delays to the clinical trials or commercial supply and distributions;
- inability to obtain manufacturing or testing slots from contract development and manufacturing organizations (including contract testing laboratories that perform cGMP operations), or CDMOs, or to have enough manufacturing slots to manufacture our product candidates to meet clinical or commercial requirements and demands;
- unfavorable FDA, EMA or other foreign or state regulatory inspection and review of a clinical trial site or records of any clinical or preclinical investigation;
- inability to procure raw materials and reagents;
- loss, depletion or performance degradation of the cell line starting material; and
- loss of or close-down of any manufacturing facility used in the manufacture of our product candidates, or the inability to find alternative manufacturing capability in a timely fashion.

Our product candidates are biologics, and the manufacture of our product candidates is complex and subject to extensive regulations. If we or our contract manufacturers fail to comply with such regulations, regulatory authorities may impose sanctions or require remedial measures that could be costly or time-consuming, and our ability to provide supply of our product candidates for clinical trials or any approved products could be delayed or stopped.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, including our existing contract manufacturers, labeling, packaging and storage facilities, and distributors, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured, tested, and stored in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and ensure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a EUA, BLA or MAA on a timely basis. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities may, at any time, audit or inspect us or any of our contract manufacturing, testing, and storage facilities involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted, and they could put a hold on one or more of our clinical trials (or could delay authorization of an EUA or approval of a BLA or MAA) if the facilities or quality systems of our or any of our CDMOs do not pass such audit or inspections. Certain of our CDMO's facilities have not yet been inspected by regulatory authorities. If any of our CDMO's facilities do not pass a pre-approval or other plant inspection, FDA or EMA approval (or authorization under EUA) of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, inspect or audit us or our CDMO's manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if compliance discrepancies with our product specifications or violations of applicable regulations occur independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business. If we or any of our CDMOs fail to maintain regulatory compliance, the FDA or EMA can impose regulatory sanctions, including, among other things, refusal to approve a pending application for a new drug product, or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be harmed. Additionally, if supply from one approved manufacturer is interrupted, there could be a significant disruption in commercial supply. An alternative manufacturer would need to be qualified and approved through a BLA and/or MAA supplement, which could result in further delay. The regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully, if approved, or could delay commercial supply once approved. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials or commercial launch may be delayed or we could lose potential revenue.

We intend to rely on third parties to manufacture, test, label, package and store clinical and commercial supplies of our product candidates.

We are currently manufacturing, testing, labeling, packaging and storing our product candidates in partnership with CDMOs. We do not own or operate any facilities for product manufacturing, labeling, packaging, storage and distribution or testing. We are dependent on third parties to manufacture, label, package, store, and distribute the clinical and commercial supplies of our current and any future product candidates. We have established a relationship with WuXi to manufacture adintrevimab for initial supply under EUA (if authorized). We have not yet fully manufactured our product candidates on a commercial scale, and cost estimates for the commercial manufacturing of our product candidates are subject to fluctuation. Certain of our product candidates may have to compete with existing and future products, such as the annual influenza vaccine, that may have a lower price point. The actual cost to manufacture our product candidates could materially and adversely affect the commercial viability of our product candidates.

The facilities used by our contract manufacturers and contract testing labs to manufacture and test our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our EUA or BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel, including their ability to adequately separate products within their multi-product manufacturing facilities to prevent cross-contamination. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We also intend to rely on third-party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. If we are not able to meet market demand for any approved product or if we are not able to produce supply at low enough costs, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business, financial condition, results of operations and prospects.

We engaged WuXi for development and generation of the production cell line starting material for adintrevimab manufacturing. The cell line expression technology used to generate the cell line is a licensed technology. Only high-level information identifying the general nature of the control elements in the expression vector has been provided to us. Details of the expression technology have not been provided, nor has there been sufficient information provided to enable a freedom-to-operate assessment of the expression technology.

In addition, we currently rely on WuXi, a CDMO in China, for clinical supply of adintrevimab and will rely on WuXi for commercial supply and supply under EUA of adintrevimab, if authorized. We will likely continue to rely on foreign CDMOs in the future. Foreign CDMOs may be subject to trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement of such material or delay or prevent the shipment of material out of the foreign country to the United States. Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our partnerships in China, which could have an adverse effect on our business, financial condition, results of operations and prospects.

Further, our reliance on third-parties for manufacturing, testing, labeling, packaging and storing our product candidates entails risks to which we would not be subject if we manufactured, tested, labeled, packaged and stored our product candidates ourselves, including:

- inability to access sufficient and timely manufacturing capacity;
- inability of our third-party manufacturers to execute our manufacturing procedures and other logistical support requirements appropriately;
- inability to negotiate additional manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- lack of ownership of the intellectual property rights in any improvements made by our third-party manufacturers in the manufacturing process for our product candidates; and
- disruptions to operations of our third-party manufacturers or suppliers by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

We cannot be sure that single-source suppliers for our manufacturing raw materials will remain in business, will not be subject to regulatory actions that impede our procurement of raw materials, or will not be purchased by one of our competitors or another company that is not interested in continuing to produce these raw materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, delays resulting in supply disruptions, diversion of resources or reduced manufacturing yields, any of which would adversely impact our business, financial condition and results of operations.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates, if authorized under EUA or approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure or total or partial suspension of production.

In July 2021, we entered into a license agreement with Biocon Biologics Limited, or Biocon, to combat COVID-19 in Southern Asia. Under the license agreement, we will provide Biocon materials and know-how to manufacture and commercialize an antibody treatment based on adintrevimab in India and select emerging markets. Biocon's ability to successfully manufacture in those territories may be restricted by foreign regulatory requirements.

We depend on sole-source third-party suppliers for materials that are necessary for the conduct of preclinical studies and manufacture and testing of our product candidates for clinical trials, and the loss of these third-party suppliers and manufacturers or their inability to supply us with sufficient quantities of adequate materials, or to do so at acceptable quality levels and on a timely basis, could harm our business.

Manufacturing and testing our product candidates requires many specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture and testing of our product candidates. For example, we are reliant on WuXi as the sole procurer of the raw materials used in the manufacture of our product candidates, including certain purification resins and cell culture media, which increases the risk of delays in production. In addition, to date, we have relied on WuXi as our only CDMO. The loss of this CDMO or its failure to supply us with material to support our clinical development program on a timely basis could impair our ability to develop our product candidates or otherwise delay the development process, which could adversely affect our business, financial condition and results of operations.

Some of our CDMO's raw material suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill-equipped to support our needs. We also do not have supply contracts with many of these suppliers directly, and we or our CDMOs may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we or our CDMOs may experience delays in receiving key raw materials and equipment to support clinical or commercial manufacturing.

For some of these specialty materials, we and our CDMOs rely on and may in the future rely on sole-source vendors or a limited number of vendors. The supply of specialty materials and equipment that are necessary to produce our product candidates could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all. Switching suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, test, manufacture and market our product candidates in a timely and competitive manner, or at all. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

The third parties upon whom we depend may be adversely affected by earthquakes, wildfires or other natural and manmade disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure, armed conflict, or other natural or manmade accidents or incidents that result in the third parties upon whom we depend from being unable to fully utilize their facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event prevented the third parties upon whom we depend from using all or a significant portion of their manufacturing facilities, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. Unforeseen natural or manmade

accidents or incidents, such as freezer failure, natural disasters or theft, could also result in loss of cell line starting material. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If the third parties on which we rely are unable to operate their facilities because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Any contamination or interruption in our manufacturing process, shortages of raw materials or failure of our suppliers of reagents to deliver necessary components could result in delays in our clinical development or commercialization schedules.

Given the nature of monoclonal antibody manufacturing, there is a risk of contamination, including in the manufacture of raw materials and in the manufacturing of our product candidates, or in the manufacturing or testing facility itself. Any contamination could adversely affect our ability to supply product candidates on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing process are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture or testing of our product candidates could adversely impact or disrupt the supply of commercial or clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently or impact product stability and expiry and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes or could impact our planned development or commercialization schedule. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments, including oral options;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA, EMA or other foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any black box warning or REMS;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to hire and retain a sales force in the United States;
- the strength of marketing and distribution support;

- the availability of third-party coverage and adequate reimbursement for adintrevimab and any other product candidates, once approved;
- the prevalence and severity of any side effects;
- any restrictions on the use of our products together with other medications or requirements that our products be used in combination with other products; and
- the ability to be effective against emerging variants as a monotherapy.

If we are unable to establish sales, marketing and distribution capabilities for adintrevimab or any other product candidate that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We are currently establishing our commercial infrastructure to support the anticipated marketing and distribution of our product candidates, which we will need to achieve commercial success for adintrevimab or any other product candidate for which we may obtain marketing approval. We are currently in the process of building a sales, marketing and market access infrastructure to market our product candidates in the United States and Europe, if they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating independent sales, marketing and market access organizations.

If we are unable to establish our own sales, marketing and distribution capabilities and are forced to enter into arrangements with, and rely on, third parties to perform these services, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

The affected populations for our lead monoclonal antibody product candidate or our other product candidates may be smaller than we or third parties currently project, which may affect our ability to enroll our clinical trials as well as the addressable markets for our product candidates.

Our projections of the number of people who are candidates to receive COVID-19 preventatives and treatments are estimates based on our knowledge and understanding of these diseases. These estimates may prove to be incorrect and new studies may further reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, and patients may not be otherwise amenable to treatment with our product candidates or may become increasingly difficult to identify and access, all of which would adversely affect our ability to enroll our clinical trials and our business, financial condition, results of operations and prospects. Further, even if we obtain approval for our product candidates, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of our product candidates.

A decline, or a widespread perception of a decline, in the spread or severity of the ongoing COVID-19 pandemic, including disease due to variants with relative or absolute resistance to other products, or an increase in available alternative

therapies for or widespread immunity to COVID-19, could reduce the total addressable market for our lead product candidate for the prevention and treatment of COVID-19. Similarly, if new SARS-CoV-2 variants are less impacted by adintrevimab and its mechanism of action than expected and such variants become more prevalent in the ongoing pandemic, the number of patients that we will be able to successfully treat with adintrevimab, if approved, will be decreased.

The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated total addressable market range for the indications we are targeting has involved using a third party to model the future populations susceptible to and immune from SARS-CoV-2, based on assumptions such as vaccine adoption, efficacy, duration of effect, viral infectiousness and other factors we cannot control. Accordingly, these estimates included in this filing may turn out to be inaccurate. Further, the data and statistical information used in this Annual Report, and in our other filings with the SEC, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

Off-label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and/or subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.

If our product candidates are approved by the FDA, we may only promote or market our product candidates for their specifically approved indications. We will train our marketing and sales force against promoting our product candidates for uses outside of the approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our products off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. Furthermore, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

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 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, investigations, and civil and criminal sanctions by the FDA, DOJ 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.

Adintrevimab and our other monoclonal antibody product candidates may face significant competition from vaccines, antiviral agents and other therapeutics for COVID-19 that are currently available or in development.

Many biotechnology and pharmaceutical companies are developing therapeutics for COVID-19 or vaccines against SARS-CoV-2, the virus that causes COVID-19. Many of these companies, which include large pharmaceutical companies, have greater resources for development and established commercialization capabilities. For example, the FDA has approved or granted EUA for several vaccines and therapeutics for the prevention or treatment of COVID-19 developed or marketed by other companies, many of which are large, established biotechnology and pharmaceutical companies. Many of these companies have also been successful in securing government funding to support research and development and/or manufacturing of their product candidates as well as government contracts to purchase their supply orders. Additional vaccines and therapeutics are in development by other pharmaceutical and biopharmaceutical companies. Given the products currently approved or authorized for use as well as those in development by others, any therapies we may develop could face significant competition. If any other company develops therapeutics more rapidly or effectively than we do, develops a therapeutic that becomes the standard of care, develops a therapeutic at a lower cost or is more successful at commercializing an approved therapeutic, we may not be able to successfully commercialize adintrevimab for the prevention and treatment of symptomatic COVID-19, even if approved, or compete with other therapeutics or vaccines, which could adversely impact our business and operations.

Many of our existing or potential competitors have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery, development and manufacture of product candidates, as well as in obtaining regulatory approvals of those product candidates in the United States and in foreign countries. Our current and potential future competitors may also have significantly more experience commercializing drugs, particularly monoclonal antibodies and other biological products, that have been approved for marketing. Furthermore, a number of our competitors have received government contracts to support research and development of their product candidates and supply orders. Mergers and acquisitions in the pharmaceutical and biotechnology industries could result in even more resources being concentrated among a small number of our competitors.

We will face competition from other drugs or from other non-drug products currently approved or that will be approved in the future for the treatment of diseases we intend to target. Therefore, our ability to compete successfully will depend largely on our ability to:

- develop and commercialize drugs that are differentiated from products in the market;
- demonstrate through our clinical trials that our product candidates are differentiated from existing and future therapies;
- attract qualified scientific, product development and commercial personnel;
- obtain patent or other proprietary protection for our medicines;
- obtain required regulatory approvals;
- obtain placement in COVID-19 prevention and treatment guidelines from organizations such as the National Institutes of Health, or NIH, CDC, WHO and the Infectious Diseases Society of America, or IDSA, and equivalent European guidelines;
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any product candidate we develop. The inability to compete with existing or subsequently introduced drugs would have an adverse impact on our business, financial condition and prospects. In addition, the reimbursement structure of approved monoclonal antibodies by other companies could impact the anticipated reimbursement structure of our monoclonal antibodies, if approved, and our business, financial condition, results of operations and prospects.

Government entities, such as the Centers for Disease Control and Prevention, or CDC, NIH, the WHO and non-government professional societies, such as the IDSA and the European Society of Clinical Microbiology and Infectious Diseases, or ESCMID, may produce treatment and/or prevention guidelines for COVID-19, including the use of monoclonal antibodies for these indications. If adintrevimab fails to be added to these guidelines, or if it receives poor positioning within those guidelines, payors and other customers may be less inclined to add adintrevimab to their formularies and/or prescribe adintrevimab, significantly reducing demand for adintrevimab, if approved.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, discovering, developing, receiving regulatory and marketing approval for, or commercializing, drugs before we do, which would have an adverse impact on our business and results of operations.

Adintrevimab may have to compete against products with Advance Purchase Agreements (APAs) from the U.S. Federal Government.

In an EUA environment where the U.S. federal government signs an Advance Purchase Agreement with a manufacturer for a specific number of doses at a fixed price, product distribution is overseen by federal and state governments and product is ordered by institutions, prescribed by physicians and administered in a variety of settings. Product is free to the institutions and patients, but patients can be billed for administration costs. Currently, all oral antivirals and monoclonal antibodies are made available under APAs. Only Gilead's intravenous antiviral, remdesivir, which received full FDA approval for treatment

of non-hospitalized patients (12 years of age or older) at high risk for COVID-19 disease progression in January 2022, is available under a standard purchase model where hospitals, clinics, and other institutions purchase product through distributors. In this environment, we may not qualify for a U.S. federal government contract. U.S. federal government contracts require contractors to meet a substantial number of qualifications, which we may not be able to meet, resulting in our inability to secure a federal contract. Additionally, our primary contract manufacturer is based in China, and the U.S. federal government may decide to avoid contracting with companies who have drug substance produced in China.

In an EUA environment where the U.S. federal government does not sign an APA, manufacturers follow a standard commercial model in which they sell product to wholesalers and/or distributors that ship the product to various sites of care. Under a standard commercial model, provider institutions and clinics can bill health plans for product. GlaxoSmithKline and Vir Biotechnology's sotrovimab was granted an EUA in May 2021 but did not receive an APA until November 2021; GlaxoSmithKline and Vir Biotechnology operated under a standard commercial model before receiving an APA.

If adintrevimab does not receive an APA but competes against products that do have an APA, adoption of adintrevimab could be limited because it would be competing against drugs that are paid for by the federal government and cost nothing to the purchasers or the patients.

Any product candidates for which we intend to seek approval as biologic products may face biosimilar competition sooner than anticipated.

If we are successful in achieving regulatory approval to commercialize any biologic product candidate that we develop, it may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biologic products subject to approval under the BLA pathway. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed by the FDA. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have an adverse effect on the future commercial prospects for our biological products.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. For example, in May 2021, the Biden administration expressed support for waiving intellectual property protections for COVID-19 vaccines amid concerns about vaccine access in foreign nations. Such waiver, if implemented, could extend to our product candidates. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our 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. If competitors are able to obtain marketing approval for biosimilars referencing our candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences.

The success of our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these therapies.

We believe our success depends on obtaining and maintaining coverage and adequate reimbursement for our product candidates, including adintrevimab for the prevention and treatment of COVID-19, and the extent to which patients will be willing to pay out-of-pocket for such products, in the absence of reimbursement for all or part of the cost. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government healthcare programs (e.g., Medicare, Medicaid, TRICARE),

managed care providers, private health insurers, health maintenance organizations, and other organizations is essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided are made on a payor-by-payor basis. One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage, and adequate reimbursement. The principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians and other healthcare professionals may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate. In addition, 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.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. Government entities, such as the CDC, the WHO and non-government professional societies, such as IDSA and ESCMID, may produce treatment and/or prevention guidelines for the prevention and treatment of COVID-19, including guidance regarding the use of monoclonal antibodies in these indications. If adintrevimab fails to be added to these guidelines, or if it receives poor positioning within these guidelines, payors and other customers may be less inclined to add adintrevimab to their formularies, significantly reducing demand for adintrevimab, if approved.

Further, increasing efforts by third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates. Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system.

There can be no assurance that adintrevimab or any other product candidate, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that it will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

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 trials and will face an even greater risk if we sell any products that we may develop. If we cannot successfully defend ourselves

against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- exhaustion of any available insurance and our capital resources;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. 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.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our or our CDMO's, CROs', manufacturers' contractors', consultants' or collaborators' cybersecurity.

Maintaining the security of our computer information systems and communication systems is a critical issue for us and we devote considerable internal and external resources to network security and other security measures to protect our systems and users, but these security measures cannot provide absolute security. The multitude and complexity of our computer systems may make them susceptible to service interruption, breaches of security, disruption of data integrity, inadvertent errors that expose our data or systems, malicious intrusion, or random attacks.

Our internal computer systems, and those of third parties on which we rely, are also vulnerable to damage from, among other things, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, system malfunctions, cyberattacks or cyber-intrusions over the Internet, attachments to emails, phishing attacks, persons inside our organization, or persons with access to systems inside our organization. We have in the past and may in the future identify defects, errors, or vulnerabilities, which could inadvertently permit access to or exposure of customer data. The risk of a security incident, breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. For example, the ongoing conflict between Russia and Ukraine has led to an increase in cyberattacks on the Ukraine, including its government, companies, institutions and people, as well on the financial and communications infrastructure of other countries, companies and individuals therein. If any such event were to occur, it could lead to the loss, destruction, alteration, prevention of access to, disclosure, dissemination of, or damage or unauthorized access to, our data (including trade secrets or other confidential information, intellectual property, proprietary business information and personal data) or data that is processed or maintained on our behalf, and cause interruptions in our operations, resulting in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, such events could lead to an interruption in our supply chain for the manufacturing of clinical and commercial drug substance and drug product, as well as related materials, and could significantly impact development and commercialization timelines and capabilities.

We cannot ensure that our data protection efforts and our investment in information technology, or the efforts or investments of CDMOs, CROs, consultants or other third parties with which we work, will prevent breakdowns or breaches in our or their systems or other cybersecurity incidents that cause loss, destruction, unavailability, alteration, dissemination of, or damage or unauthorized access to, our data, including personal data, assets and other data processed or maintained on our behalf, that could have a material adverse effect upon our reputation, business, operations or financial condition. We also rely on third parties to manufacture our product candidates, and any data breaches or other security events relating to their computer systems could also have a material adverse effect on our business. Controls employed by our information technology department and our CDMOs, CROs, consultants and other third parties could prove inadequate, and our ability to monitor such

third parties' data security practices is limited. Due to applicable laws, rules, regulations and standards or contractual obligations, we may be held responsible for any information security failure or cyberattack attributed to our third-party service providers as they relate to the information we share with them.

Notifications and follow-up actions related to a data breach or other security incident could impact our reputation and cause us to incur significant costs, including significant legal expenses and remediation costs. We expect to incur significant costs in an effort to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security incident. However, we cannot guarantee that we will be able to detect or prevent any such incidents, or that we can remediate any such incidents in an effective or timely manner. Our efforts to improve security and protect data from compromise may also identify previously undiscovered instances of data breaches or other cybersecurity incidents. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information or personal data, we could incur material legal claims and liability and damage to our reputation, and the further development of our product candidates could be delayed. Any such event could also compel us to comply with federal and state breach notification laws, and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to substantial liability under laws, rules, regulations and standards that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

The effects of a security breach or privacy violation could be further amplified during the current COVID-19 pandemic. In addition, the cost and operational consequences of implementing further data protection measures could be significant, and theft of our intellectual property or proprietary business information could require substantial expenditures to remedy. Further, we cannot be certain that our liability insurance will be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related breaches, such coverage will cover any indemnification claims against us relating to any incident, will continue to be available to us on economically reasonable terms, or at all, or any insurer will not deny coverage as to any future claim. The successful assertion of one or more large claims against us that exceed available insurance coverage, or the occurrence of changes in our insurance policies, including premium increases or the imposition of large deductible or co-insurance requirements, could adversely affect our reputation, business, financial condition and results of operations.

We are subject to a variety of privacy and data security laws, rules, regulations, policies, industry standards and contractual obligations, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws and federal and state consumer protection laws. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations, including Section 5 of the Federal Trade Commission Act, that govern the collection, use, disclosure and protection of health-related and other personal information. In addition, we may obtain health information from third parties, including research institutions from which we obtain clinical trial data, that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

In Europe, the General Data Protection Regulation, or the GDPR, took effect in May 2018. The GDPR governs the collection, use, disclosure, transfer or other processing of personal data of individuals within the European Economic Area, or the EEA, including clinical trial data. Among other things, the GDPR imposes requirements regarding the security of personal data and notification of data breaches to the competent national data processing authorities, requires having lawful bases on which personal data can be processed and requires changes to informed consent practices, as well as more detailed notices for clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws; in July 2020, the Court of Justice of the European Union limited how organizations could lawfully transfer

personal data from the EEA to the United States by invalidating the EU-U.S. Privacy Shield and imposing further restrictions on the use of standard contractual clauses, which could increase our costs and our ability to efficiently process personal data from the EEA. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our annual global turnover) and 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.

Relatedly, following the United Kingdom's withdrawal from the EEA and the European Union and the expiration of the Transition Period, companies must comply with both the GDPR and the legislation similar to the GDPR as incorporated into UK national law, which provides for significant fines of up to the greater of £17.5 million or 4% of global turnover and exposes companies to two parallel regimes with potentially divergent enforcement actions for certain violations. On January 1, 2021, the United Kingdom became a third country for purposes of the GDPR. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example with respect to how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. Pursuant to the EU-UK Trade and Cooperation Agreement of December 24, 2020, transfers of personal data from the European Union to the United Kingdom may continue to take place without a need for additional safeguards during a further transition period, which expires on the earlier of (i) the date on which an adequacy decision with respect to the United Kingdom is adopted by the European Commission; or (ii) the expiry of four months, which shall be extended by a further two months unless either the European Union or the United Kingdom objects. On June 28, 2021 the European Commission formally adopted its adequacy decision finding the United Kingdom to be adequate under the GDPR.

Compliance with these and any other applicable privacy and data security laws and regulations is a rigorous and time-intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. If we fail to comply with any such laws or regulations, we may face significant fines and penalties that could adversely affect our business, financial condition and results of operations. Furthermore, the laws are not consistent, and compliance in the event of a widespread data breach is costly. In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, California enacted the California Consumer Privacy Act, or the CCPA, which took effect on January 1, 2020, became enforceable by the California Attorney General on July 1, 2020 and has been dubbed the first "GDPR-like" law in the United States. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, California voters approved a new privacy law, the California Privacy Rights Act, or the CPRA, in the November 3, 2020 election, which will impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. Although the CCPA currently exempts certain health-related information, including clinical trial data, the CCPA and the CPRA may increase our compliance costs and potential liability. Similar laws have been proposed in other states and at the federal level and, if passed, such laws may have potentially conflicting requirements that would make compliance challenging. For example, on March 2, 2021, Virginia enacted the Virginia Consumer Data Protection Act, or CDPA, which becomes effective on January 1, 2023, and on June 8, 2021, Colorado enacted the Colorado Privacy Act, or CPA, which takes effect on July 1, 2023. The CPA and CDPA are similar to the CCPA and CPRA but aspects of these state privacy statutes remain unclear, resulting in further legal uncertainty.

With the GDPR, CCPA, CPRA, CDPA, CPA and other laws, regulations and other obligations relating to privacy and data protection imposing new and relatively burdensome obligations, and with the substantial uncertainty over the interpretation and application of these and other obligations, we may face challenges in addressing their requirements and making necessary changes to our policies and practices and may incur significant costs and expenses in an effort to do so. We are currently in the process of developing and updating our policies and procedures in accordance with requirements under applicable data privacy and protection laws and regulations. We do not currently have any formal data privacy policies and procedures in place and have not completed formal assessments of whether we are in compliance with all applicable data privacy laws and regulations. Additionally, if third parties with which we work, such as vendors or service providers, violate applicable laws, rules or regulations or our policies, such violations may also put our or our clinical trial and employee data, including personal data, at risk, which could in turn have an adverse effect on our business.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. 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 use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. 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, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could seriously harm our business.

Risks Related to Our Dependence on Third Parties

We currently rely on third parties to conduct, supervise, analyze and monitor a significant portion of our research and preclinical testing and clinical trials for our product candidates, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We have engaged CROs and other third parties to conduct our planned preclinical studies or clinical trials, including our ongoing clinical trials of adintrevimab, and to monitor and manage data. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, to conduct those clinical trials. We also rely on third parties for their research and discovery capabilities. Any of these third parties may terminate their engagements with us, some in the event of an uncured material breach and some at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Further, the performance of our CROs and other third parties conducting our trials may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO or clinical site or other vendor staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic.

In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We rely on these parties for execution of our preclinical studies and clinical trials, and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities

but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval for adintrevimab or any other product candidates.

We also expect to rely on other third parties to label, store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

We may seek collaborations with third parties for the development or commercialization of our product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.

We may seek third-party collaborators for the development and commercialization of our product candidates, including for the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any such arrangements include regional and national pharmaceutical companies and biotechnology companies. If we enter into any additional such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. For example, our agreement with Biocon may not result in the successful development and commercialization of an antibody treatment for COVID-19 in India or other markets.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for our current and future product candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours and our ability to successfully develop and commercialize our product candidates may be adversely affected.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidates and technologies. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and product candidates. The risks associated with patent rights generally apply to patent rights that we in-license now or in the future, as well as patent rights that we may own now or in the future. We currently own two issued U.S. patents with claims directed to adintrevimab and ADG10, respectively, and one allowed U.S. patent application with claims directed to methods of use of adintrevimab, alone or in combination with ADG10, which is projected to issue within the next few months. In addition, although we own a number of pending patent applications, we may not be successful in

prosecuting our filed patent applications to obtain issuance of additional patents. Accordingly, there can be no assurance that we will be able to obtain patent protection for our product candidates. Our pending Patent Cooperation Treaty, or PCT patent applications, are not eligible to become issued patents until, among other things, we file a national stage patent application within 30 months in the countries in which we seek patent protection. Furthermore, our pending U.S. provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional U.S. patent application within one year of filing of the U.S. provisional patent application with the United States Patent and Trademark Office, or the USPTO. If we do not timely file any national stage patent applications or non-provisional U.S. patent applications, we may lose our priority date with respect to our PCT and provisional U.S. patent applications, and any patent protection on the inventions disclosed in such patent applications. We can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. In addition, the coverage claimed in any such patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Failure to obtain and maintain such issued patents could have a material adverse effect on our ability to develop and commercialize our product candidates.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our resulting or granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product, that would be competitive with one or more of our product candidates. There is no assurance that all the potentially relevant prior art relating to our patent and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our future licensors were the first to file any patent application related to our product candidates and technologies. We additionally cannot guarantee that our employees, former employees or consultants will not file patent applications claiming our inventions. Because of the "first-to-file" laws in the United States, such unauthorized patent application filings may defeat our attempts to obtain patents on our own inventions. If a third party can establish that we or our licensors were not the first to make or the first to file for patent protection of such inventions, our owned or licensed patent applications may not issue as patents and, even if issued, may be challenged and invalidated or rendered unenforceable. Additionally, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the USPTO, challenging the validity of one or more claims of our owned or licensed patents. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one of our owned or licensed pending patent applications. A third party may also claim that our owned or licensed patent rights are invalid or unenforceable in litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Any successful challenge to any patents owned by or licensed to us after patent issuance could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could deprive us of rights necessary for the successful commercialization of any of our product candidates and technologies that we may develop. Even if they are unchallenged or such third-party challenges are unsuccessful, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates and technologies or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent and patent applications we hold, obtain or pursue with respect to our product candidates and technologies is challenged, or if they fail to provide meaningful exclusivity for our product candidates and technologies, it could threaten our ability to commercialize our product candidates and technologies. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection, if approved, would be reduced.

The patent prosecution process is expensive and time-consuming. We may not be able to prepare, file and prosecute all necessary or desirable patent applications at a commercially reasonable cost, in a timely manner or in all jurisdictions. It is also possible that we may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Any of the foregoing could have an adverse impact on our business and results of operations.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection provided by our patent estate, we rely on trade secret protection and confidentiality agreements to protect proprietary scientific, business and technical information and know-how that is not or may not be patentable or that we elect not to patent. We seek to protect our proprietary information, data and processes, in part, by confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and partners. Although these agreements are designed to protect our proprietary information, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed with all third parties who may have helped to develop our intellectual property or who had access to our proprietary information, or that our agreements will not be breached. If any of the parties to these confidentiality agreements breaches or violates the terms of such agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result.

Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Trade secrets and know-how can be difficult to protect as trade secrets and know-how will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Moreover, our competitors and other third parties may independently develop knowledge, methods and know-how equivalent to our trade secrets. Competitors and other third parties could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or violate our intellectual property rights, design around our protected technology or develop their own technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets and proprietary know-how were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems.

Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective.

While we have confidence in these individuals, organizations and systems, our agreements or security measures may be breached, and we may not have adequate remedies for any breach. Also, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Patent terms may be inadequate to protect our competitive position on our products for an adequate amount of time, and if we do not obtain protection under the Hatch-Waxman Amendments and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited.

Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic and other competing medications. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates may expire before or shortly after such candidates are commercialized. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit 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. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, fail to exercise due diligence during the testing phase or regulatory review process, or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension, or if the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened, and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, which could have a material adverse effect on our business.

We are a party to an assignment and license agreement with Adimab, pursuant to which we are obligated to make payments upon achievement of milestone events and royalties. If this agreement is terminated, our business and prospects will be materially and adversely affected.

We are party to an assignment and license agreement, or the Adimab Assignment Agreement, with Adimab, LLC, or Adimab, which has assigned to us its rights to all existing coronavirus antibodies controlled by it and their derivatives, patents claiming such antibodies, know-how related to such antibodies, and biological and chemical materials specifically related to such antibodies. Pursuant to the Adimab Assignment Agreement, Adimab additionally grants us a non-exclusive, worldwide, sublicensable license under Adimab's antibody discovery and optimization platform technology to research, develop, make, use, and sell coronavirus antibodies and products containing or comprising coronavirus antibodies, provided that we may not use such licensed rights to discover or optimize antibodies. Under the Adimab Assignment Agreement, we are required to use commercially reasonable efforts to achieve specific development and regulatory milestones for products in certain major markets and to commercialize a product in any country in which we obtain marketing approval. This agreement additionally contains obligations that require us to make payments in the event certain milestone events are achieved and royalty payments on net sales of our products, if approved, on a product-by-product and country-by-country basis, for a period ending on the later of 12 years after the first commercial sale of such product in such country or the expiration of the last valid claim of any patent in such country that was assigned to us under the Adimab Assignment Agreement or that claims priority to any such patent. Our business is reliant upon the intellectual property rights assigned and licensed to us under the Adimab Assignment Agreement. If we materially breach the Adimab Assignment Agreement, our license under the Adimab Assignment Agreement can be terminated, we can be required to return to Adimab the assigned patent rights and any patents or patent applications that claim priority to such patents, our rights to develop and commercialize our product candidates will be adversely affected, and we could be found liable for substantial monetary damages. If the Adimab Assignment Agreement is terminated as a result of our breach or otherwise, our business and prospects will be materially and adversely affected.

Our rights to develop and commercialize our product candidates are subject, in part, to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We rely on licensed intellectual property rights and intend to periodically explore a variety of additional possible strategic collaborations or licenses in an effort to gain access to additional product candidates, technologies or resources. At this time, we cannot predict what form such strategic collaborations or licenses might take in the future. We are likely to face significant competition in seeking appropriate strategic collaborators, and strategic collaborations and licenses can be complicated and time-consuming to negotiate and document. We may not be able to negotiate strategic collaborations on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any additional strategic collaborations or licenses because of the numerous risks and uncertainties associated with establishing them. Any delays in entering into new strategic collaborations or licenses related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

Our current and future collaborations and licenses could subject us to a number of risks, including:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to comply with various development, diligence, commercialization and other obligations and meet development timelines, or exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses (for example, under the Adimab Assignment Agreement, we are required to use commercially reasonable efforts to achieve specified development and regulatory milestones for products in certain major markets and to commercialize a product in any country in which we obtain marketing approval);
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- we may not have the right to control the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license, and we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business (for example, we have no rights to control the preparation, filing, prosecution or maintenance of the patents licensed to us under Adimab's antibody discovery and optimization platform technology under the Adimab Assignment Agreement);
- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenue from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

Disputes may arise with respect to our current or future licensing agreements, including in connection with any of the forgoing, and, in spite of our efforts, our current and future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements.

Our license agreements are, and future license agreements are likely to be, 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, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

Furthermore, license agreements we enter into in the future may not provide exclusive rights to use intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products. Patents licensed to us could be put at risk of being invalidated or interpreted narrowly in litigation filed by or against our licensors or another licensee or in administrative proceedings brought by or against our licensors or another licensee in response to such litigation or for other reasons. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and licensed patents, and the enforcement or defense of our licensed patents or future owned patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection.

For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to United States patent law. These included provisions that affect the way patent applications are prosecuted and also affect patent litigation. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to challenge the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review and derivation proceedings. Finally, the Leahy-Smith Act contained new statutory provisions that require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future patents. Further, the United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the United States Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have owned or licensed or that we might obtain in the future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Similarly, changes in patent laws and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we may obtain in the future. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance in a given country of a patent covering an invention is not followed by the issuance in other countries of patents covering the same invention, or if any judicial interpretation of the validity, enforceability or scope of the claims or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

We may be involved in lawsuits to protect or enforce our future patents, the patents of our licensors or our other intellectual property or proprietary rights, which could be expensive, time consuming and unsuccessful and our future issued patents and the patents of our licensors covering our product candidates could be found invalid or unenforceable.

Competitors or other third parties may infringe, misappropriate or otherwise violate the patents of our licensors or any patents issued as a result of our pending or future patent applications. To counter infringement, misappropriation or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid, is unenforceable or is not infringed, or may refuse to stop the other party in such infringement proceeding from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our licensed or future owned patents at risk of being invalidated, held unenforceable or interpreted narrowly, and could put any of our owned or licensed patent applications at risk of not yielding an issued patent.

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, *inter partes* review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings, nullity proceedings or litigation or invalidation trials or invalidation proceedings). Such proceedings could result in revocation of or amendment to our future patents in such a way that they no longer cover our product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patent applications, should they issue as patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates.

Interference or derivation proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions or inventorship (and possibly also ownership) of inventions with respect to our patent applications or resulting patents, or patent applications or resulting patents of third parties. For example, we were notified in October 2020 that a third party claimed that one of its employees should be listed as an inventor on certain of our patent applications claiming SARS-COV-2 binding antibodies or their preparation; however, we believe such claim, if valid, would be limited to only a predecessor antibody to adintrevimab and, in any event, is without merit. The entity that assigned to us the relevant patent applications is required to indemnify us with respect to any potential financial ramifications relating to this claim. However, an unfavorable outcome in this claim or any other inventorship or ownership dispute could result in the loss of our exclusive rights in our technology and the associated intellectual property rights, require us to cease using the related technology or force us to take a license under the patent rights of the prevailing party, if available. Furthermore, our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Furthermore, any successful claim of inventorship by a third party could result in the loss of priority for our patent applications, potentially resulting in subsequently filed third-party patent applications having priority over our patent applications and thereby precluding our ability to obtain patent protection for the inventions claimed in our patent applications. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, infringement, misappropriation or other violations of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States. For the patents and patent applications that we have licensed, we may have limited or no right to participate in the defense of any licensed patents against challenge by a third party. An adverse result in any litigation or defense proceedings could put one or more of our or our licensors' patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could have a material adverse impact on our business.

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, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any of the foregoing could materially adversely affect our business, results of operations and financial condition.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, WuXi has provided only high-level information to us identifying the general nature of the licensed control elements in the expression vector used in the production cell line starting material for adintrevimab manufacturing. Details of the expression technology have not been provided, nor has there been sufficient information provided to enable a freedom-to-operate assessment of the expression technology. We therefore cannot be sure that we have licensed all intellectual property rights that are relevant to or necessary for the commercialization of adintrevimab, and a third party may claim that our development or commercialization of adintrevimab infringes its intellectual property rights. We could be required to acquire or obtain a license to such intellectual property from such third parties, and we may be unable to do so on commercially reasonable terms or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights, we may be required to redesign our manufacturing process for adintrevimab, which may not be feasible on a technical or commercial basis in a timely manner, and we may have to delay or abandon development of adintrevimab, which could have a material adverse effect on our business.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant third-party patents may negatively impact our ability to develop and market our products.

We may be unsuccessful in licensing or acquiring intellectual property from third parties that may be required to develop and commercialize our product candidates.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if we are able to in-license any such necessary intellectual property, it could be on a non-exclusive basis, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and we also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to redesign our product candidates, which may not be feasible on a technical or commercial basis, and we may have to delay or abandon development of the relevant program or product candidate, which could have a material adverse effect on our business.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain.

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents, trademarks, and proprietary rights of third parties. As our current and future product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There is a substantial amount of litigation involving patents, trademarks, and other intellectual property rights in the biotechnology and pharmaceutical industries, including infringement lawsuits, interferences, derivation proceedings, post grant reviews, *inter partes* reviews, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and 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 manufacture of our product candidates and technologies. Third

parties, including our competitors may initiate legal proceedings against us alleging that we are infringing, misappropriating or otherwise violating their patents, trademarks, or other intellectual property rights.

We cannot provide any assurance that our current and future product candidates do not infringe, misappropriate or otherwise violate other parties' patents, trademarks, or other proprietary rights, and competitors or other parties may assert that we infringe, misappropriate or otherwise violate their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our current and future product candidates, including oppositions, interference proceedings, reexaminations, post-grant review, *inter partes* review, or derivation proceedings before the USPTO in the United States or any equivalent regulatory authority in other countries. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could have a negative impact on our ability to commercialize adintrevimab or any future product candidates. In order to successfully challenge the validity of any United States patents asserted against us in federal court, we would need to overcome a presumption of validity. As this burden is high and requires us to present clear and convincing evidence as to the invalidity of any such United States patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such United States patent. Moreover, given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future.

While we may decide to initiate proceedings to challenge the validity of these or other patents in the future, we may be unsuccessful, and courts or patent offices in the United States and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that one of our product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. In addition, third parties may obtain patents in the future and claim that our product candidates or technologies infringe upon these patents. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe, misappropriate or otherwise violate a third party's valid intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. For example, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease developing, manufacturing and commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the patent at issue. We may also be required to indemnify collaborators or contractors against such claims. A finding of infringement, misappropriation or other violation of third-party intellectual property rights could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology. 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 litigation. There could also be public announcements of the results of hearings,

motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

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

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors 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 confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. 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. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

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

We may also be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents issued as a result of our pending or future applications, or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates. Although it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to enforce our rights or to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We rely on third parties to manufacture our product candidates, and we collaborate with additional third parties for the development of such product candidates. We therefore must, at times, share trade secrets with them. We may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure could have an adverse effect on our business and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be

effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors have patent protection, but enforcement rights are not as strong as those in the United States or Europe. These products may compete with our product candidates, and our future patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we or our licensors may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

While we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished, and we may face additional competition from others in those jurisdictions.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property rights, especially those relating to life sciences, which could make it difficult for us to stop the infringement, misappropriation or other violation of our future patents or marketing of competing products in violation of our proprietary rights generally. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Moreover, our and our licensors' ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Proceedings to enforce our or our licensors' patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our future patents or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensors at risk of not issuing as patents, and could provoke third parties to assert claims against us. We and our licensors may not prevail in any lawsuits that we or our licensors initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license from third parties.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business,

our competitive position may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

For example, our license agreement with Biocon pursuant to which we will provide Biocon materials and know-how to manufacture and commercialize an antibody treatment based on adintrevimab in India and select emerging markets may also expose us to risks related to enforcement of our intellectual property rights.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government 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 government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may obtain in the future. Furthermore, the USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals and rely on such third parties to help us comply with these requirements and effect payment of these fees with respect to the patent and patent applications that we own, and we rely upon our licensors to comply with these requirements and effect payment of these fees with respect to any patents and patent applications that we license. In many cases, an inadvertent lapse of a patent or patent application can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market, which could have a material adverse effect on our business.

Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business.

We expect to rely on trademarks as one means to distinguish our product candidates, if approved for marketing, from the drugs of our competitors. We also expect to rely on trademarks to protect our company name. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. We currently have trademark applications pending in the United States and in certain foreign jurisdictions, but we have no issued trademark registrations in the United States. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. If we are found to infringe a third party's trademark rights, we could be forced to rebrand our company or our drugs, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Over the long term, if we are unable to establish name recognition based on our trademarks, then we may not be able to compete effectively, and our competitive position, business, financial condition, results of operations and prospects may be significantly harmed. Moreover, any name we propose to use with our product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Any of the foregoing events may have a material adverse effect on our business.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of any of our patents, should they issue;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor;

- we or our collaborators might not have been the first to make the inventions covered by our future issued patents or our pending patent applications;
- we or our collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

Risks Related to Legal and Regulatory Compliance Matters

Our relationships with customers, healthcare providers, including physicians, and third-party payors are subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, including physicians, and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from 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 in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for 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. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the United

States federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. 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;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. 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 laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to: (i) payments or other "transfers of value'' made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could harm our business.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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 robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain regulatory approval for adintrevimab or any future product candidates, they will remain subject to ongoing regulatory oversight, which may result in significant additional expense.

Even if we obtain any regulatory approval for adintrevimab or any future product candidates, they will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submission of safety and other post-market information, among other things. Any regulatory approvals that we receive for adintrevimab or any future product candidates may also be subject to a REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval, or requirements that we conduct potentially costly post-marketing testing and surveillance studies, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports.

Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We will also have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drug products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we will not be allowed to promote our products for indications or uses for which they do not have approval, commonly known as off-label promotion. The holder of an approved BLA must submit new or supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process. A company that is found to have improperly promoted off-label uses of their products may be subject to significant civil, criminal and administrative penalties.

In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a drug, such as adverse events of unanticipated severity or frequency, or problems with the facility where the drug is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of adintrevimab or any future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending marketing application or supplement to an approved application or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of products or product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize adintrevimab or any future product candidates and harm our business, financial condition, results of operations and prospects.

Even if we obtain authorization under an EUA or FDA or EMA approval any of our product candidates in the United States or European Union, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. In addition, in order to distribute adintrevimab, if authorized under an EUA, we will need to secure and maintain required state licenses.

Approval by the FDA in the United States or the EMA in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional preclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers and significantly impacts the United States pharmaceutical industry. The ACA, among other things contains a number of provisions of particular import to the pharmaceutical and biotechnology industries, including, but not limited to, those governing enrollment in federal healthcare programs, 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, and annual fees based on pharmaceutical companies' share of sales to federal healthcare programs.

There have been executive, judicial and congressional challenges to certain aspects of the ACA. While the United States Congress has not passed comprehensive repeal legislation, several bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Act, included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." On June 17, 2021, the U.S. Supreme Court dismissed on procedural grounds a challenge that argued that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the ACA will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how the Supreme Court ruling, other such litigation and the healthcare reform measures of the Biden administration will impact the ACA or our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA and the Infrastructure Investment and Jobs Act, will remain in effect through 2031, unless additional congressional action is taken. However, COVID-19 relief

legislation suspended the 2% Medicare sequester from May 1, 2020 through March 31, 2022. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single-source and innovator multiple-source drugs, beginning January 1, 2024. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding, which could have an adverse effect on customers for our product candidates, if approved, and, accordingly, our financial operations.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this rule has been delayed until January 1, 2026. Further, in November 2020, CMS issued an interim final rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021 and ending December 31, 2027. As a result of litigation challenging the MFN Model, on December 27, 2021, CMS published a final rule that rescinded the MFN Model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to the executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue to advance these principles. In addition, Congress is considering drug pricing as part of other reform initiatives. 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, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. It is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for adintrevimab or any future product candidates. We cannot determine how changes in regulations, statutes, policies or interpretations when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements or discontinuance of one or more of our products, if approved; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of adintrevimab or other product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition and results of operations.

Risks Related to Employee Matters and Managing Our Growth

Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the management, development, clinical, financial and business development expertise of our executive officers. Each of our executive officers may currently terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees, including the recently announced transitions of Tillman U. Gerngross, Ph.D. as Chief Executive Officer and Lynn Connolly, M.D. as Chief Medical Officer, could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees, including our current search for a permanent Chief Executive Officer, may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Certain of our directors, officers and key employees may have actual or potential conflicts of interest because of their positions with Adimab and/or other companies and may not be able to or may choose not to devote sufficient time and attention to our company, or may otherwise have conflicting incentives.

Laura Walker, Ph.D., our co-founder and Chief Scientific Officer, serves as Senior Director of Antibody Sciences at Adimab. Terrance McGuire and Ajay Royan, members of our board of directors, serve as directors of Adimab. Other of our directors and officers also serve on the boards of directors of other private and public companies. As a result, these individuals may not be able to devote their full time and attention to our company, which could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Since joining us, all of our executive officers have each spent a significant portion of their time devoted to us. While none of the executives has a minimum time commitment to us, each retains flexibility to ensure that he or she can re-allocate his or her time based on the needs of each business. These executives' time-allocation strategies may change over time based on the needs of each business or the executives' individual incentives to provide services to us relative to other businesses. In addition, certain of these individuals are beneficial owners of equity interests in Adimab. These individuals' respective positions at Adimab and the ownership of any Adimab equity or equity awards creates, or may create the appearance of, conflicts of interest, including when these individuals make decisions that could have different implications for Adimab than for us.

Adimab owns a significant percentage of our common stock, will be able to exert significant influence over matters subject to stockholder approval and may have interests that conflict with those of our other stockholders.

Adimab is currently our largest stockholder and beneficially owns approximately 25.1% of the voting power of our outstanding common stock as of February 1, 2022 on an as-converted basis. As such, Adimab has the ability to substantially influence us through this ownership position. For example, Adimab, acting together with a small number of our other large stockholders, will be able to control elections of directors, amendments of our organizational documents or approval of any merger, amalgamation, sale of assets or other major corporate transaction. Any transferees or successors of all or a significant portion of Adimab's ownership in us will be able to exert a similar amount of influence over us through their ownership position.

Furthermore, certain of our directors, officers and key employees may have actual or potential conflicts of interest with us because of their positions or affiliations with Adimab or their beneficial ownership of equity in Adimab. Laura Walker, Senior Director of Antibody Sciences at Adimab, and Terrance McGuire and Ajay Royan, members of the board of directors of Adimab, serve on our leadership team and/or on our board of directors and retain their positions and affiliations with Adimab. Our other stockholders may not have visibility into the Adimab ownership positions or other affiliations of any of our directors or officers with Adimab or its affiliates, which may change at any time through acquisition, disposition, dilution or otherwise. Any change in our directors' or officers' ownership in or positions with Adimab or its affiliates could impact the interests of those holders. Adimab's interests may not always coincide with our corporate interests or the interests of our other stockholders, and it may exercise its voting and other rights in a manner with which you may not agree or that may not be in the best interests of our other stockholders. So long as it continues to own a significant portion of our outstanding voting securities, Adimab will continue to have considerable influence in all matters that are subject to approval by our stockholders and will be able to strongly influence our other decisions.

We may expand our clinical development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

Depending on our development progresses, we may experience growth in the number of our employees and the scope of our operations, particularly in the areas of clinical product development, regulatory affairs, manufacturing and, if any of our product candidates receives marketing approval, sales, marketing and distribution. To manage our potential future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter 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, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

Risks Related to Ownership of Our Common Stock and Our Status as a Public Company

An active trading market for our common stock may not continue to be developed or sustained.

Prior to our initial public offering, there was no public market for our common stock. Although our common stock is listed on the Nasdaq Global Market, if an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares at an attractive price or at all.

The trading price of the shares of our common stock has been and may continue to be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. Since our initial public offering and through March 24, 2022, our common stock has traded at prices ranging from $4.05 to $78.82 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the timing, progress and results of our ongoing clinical trials of adintrevimab or the commencement, enrollment or results of any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for adintrevimab or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of adintrevimab or any other product candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- announcements by our competitors of new product candidates or technologies, or the results of clinical trials or regulatory decisions;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock,

regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

We previously identified a material weakness in our internal control over financial reporting. We may identify future material weaknesses in our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we fail to establish and maintain adequate internal control over financial reporting, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective, which may adversely affect our business.

We previously identified a material weakness in our internal control over financial reporting that was identified during the preparation of our March 31, 2021 financial statements. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim condensed consolidated financial statements will not be prevented or detected on a timely basis.

Although we have determined that the previously identified material weakness has been remediated as of December 31, 2021, we cannot assure you that we will not identify other material weaknesses in the future, which could negatively impact our results of operations in future periods.

Ensuring that we have adequate internal control over financial reporting in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with our initial public offering, we began the process of documenting, reviewing and improving our internal control over financial reporting for compliance with the rules and regulations of the Securities and Exchange Commission, or SEC, which requires annual management assessment of the effectiveness of our internal control over financial reporting.

Implementing any appropriate changes to our internal control over financial reporting 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 establishing and 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.

Further, if we are unable to meet the demands that have been placed upon us as a public company, including the rules and regulations of the SEC, we may be unable to accurately report our financial results in future periods, or report them within the timeframes required by law or stock exchange regulations. Failure to comply with the rules and regulations of the SEC, when and as applicable, could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. Any failure to maintain or implement required effective internal control over financial reporting, or any difficulties we encounter in their implementation, could result in additional material weaknesses, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Furthermore, if we cannot provide reliable financial reports or prevent material misstatements due to fraud or error, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities, which could require additional financial and management resources.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. As a newly public company, we have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more

equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

A significant portion of our total outstanding shares are available for immediate resale. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly.

In addition, we have filed registration statements on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, registering the issuance of shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options and the restrictions of Rule 144 in the case of our affiliates.

Additionally, the holders of an aggregate of approximately 44.0 million shares of our common stock, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares 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.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors will have the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents will also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors will be elected each year;
- stockholders will not be entitled to remove directors other than by a $66^{2}/_{3}\%$ vote and only for cause;
- stockholders will not be permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

In addition, we are subject to the anti-takeover provisions of Section 203 of the Delaware General Corporation Law, which regulates corporate acquisitions by prohibiting Delaware corporations from engaging in specified business combinations with particular stockholders of those companies. These provisions could discourage potential acquisition proposals and could delay or prevent a change of control transaction. They could also have the effect of discouraging others from making tender offers for our common stock, including transactions that may be in your best interests. These provisions may also prevent changes in our management or limit the price that investors are willing to pay for our stock.

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our executive officers, directors and current beneficial owners of five percent or more of our common stock and their respective affiliates beneficially own a majority of our outstanding common stock. As a result, these persons, acting together,

would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the current market price of our common stock and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer," our annual gross revenues exceed $1.07 billion or we issue more than $1.0 billion of non-convertible debt in the previous three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure.
- an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation;
- exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements.

We cannot predict whether investors will find our common stock less attractive if we 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 reduced or more volatile. 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 allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

We are a "smaller reporting company" and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a "smaller reporting company" as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act. We are therefore entitled to rely on certain reduced disclosure requirements for as long as we remain a smaller reporting company, such as an exemption from providing selected financial data and certain executive compensation information. In addition, for as long as we are a smaller reporting company with less than $100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404(b) of the Sarbanes-Oxley Act.

These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company may make it harder for investors to analyze our results of operations and financial prospects. 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 prices may be more volatile.

We have broad discretion in the use of our cash, cash equivalents and marketable securities, including the net proceeds from our initial public offering.

We have broad discretion over the use of our cash, cash equivalents and marketable securities, including the net proceeds from our initial public offering. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. Our failure to apply our cash, cash equivalents and marketable securities effectively could compromise our ability to pursue our growth strategy and we might not be able to yield a significant return, if any, on our investment of our cash, cash equivalents and marketable securities. You will not have the opportunity to influence our decisions on how to use our cash, cash equivalents and marketable securities.

Because we do not anticipate paying any cash dividends on our common stock in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our common stock to provide dividend income. We have not declared or paid cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future. Investors seeking cash dividends should not purchase our common stock.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law, our amended and restated certificate of incorporation, or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations and prospects.

These exclusive forum provisions may result in increased costs for investors to bring a claim. Further, these exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

We have incurred and will continue to incur increased costs and demands upon management as a result of becoming a public company, which could lower our profits or make it more difficult to run our business.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company, including costs associated with public company reporting requirements. We also have incurred and will continue to incur costs associated with the Sarbanes-Oxley Act, and related rules implemented by the SEC and the Nasdaq Stock Market. The expenses generally incurred by public companies for reporting and corporate governance purposes have been increasing. We expect these rules and regulations to increase our legal and financial compliance costs and to make some activities more time-consuming and costly, although we are currently unable to estimate these costs with any degree of certainty. These laws and regulations also could make it more difficult or costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These laws and regulations could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on our board committees, or as our executive officers. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of our common stock, fines, sanctions, other regulatory action and potentially civil litigation.

In particular, pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, in our second annual report on Form 10-K due to be filed with the SEC after becoming a public company, we will be required to furnish a report by our management on our internal control over financial reporting. However, 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. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing whether such controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting.

Our ability to use net operating losses to offset future taxable income may be subject to certain limitations.

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any. As of December 31, 2021, we had U.S. federal net operating loss, or NOL, carryforwards of $221.9 million, which may be available to reduce future taxable income and have an indefinite carryforward period but are limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2021, we had state NOL carryforwards of $81.9 million, which may be available to reduce future taxable income, of which $3.4 million have an indefinite carryforward period while the remaining $78.5 million begin to expire in 2041. As of December 31, 2021, we also had U.S. federal and state research and development tax credit carryforwards of $3.3 million and $1.3 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2041 and 2036, respectively.

Under the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act, or the CARES Act, federal NOLs incurred in taxable years beginning after December 31, 2017 and in future taxable years may carry forward indefinitely, but the deductibility of such federal NOLs incurred in taxable years beginning after December 31, 2020 may be limited. It is uncertain how various states will respond to the Tax Act and the CARES Act. In addition, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income or taxes may be limited. Our initial public offering, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced, and may in the future experience, ownership changes as a result of shifts in our stock ownership, some of which may be outside of our control. If an ownership change has occurred or occurs in the future, and our ability to use our NOL carryforwards is materially limited, it would harm our financial condition and results of operations by effectively increasing our future tax obligations.

We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. Beginning in 2022, the Tax Act eliminates the currently available option to deduct research and development expenditures and requires taxpayers to amortize them over five years. The U.S. Congress is considering legislation that would defer the amortization requirement to future periods; however, there is no assurance that the provision will be repealed or otherwise modified. If the requirement is not repealed or modified, it will have a material impact on our cash flows beginning in 2022.

Our business activities will be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

As we expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or 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 most recently from December 22, 2018 to January 25, 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. The FDA is currently conducting mission-critical and other limited foreign inspections and is planning more foreign inspections beginning in April 2022, and resumed planning and conducting domestic surveillance inspections on February 7, 2022. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Unfavorable global economic conditions and geopolitical events could adversely affect our business, financial condition or results of operations, including clinical trials.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The financial markets and the global economy may also be adversely affected by the current or anticipated

impact of military conflict, including the ongoing conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact our clinical trials, the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Portions of our future clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Some of our clinical trial sites are in regions impacted by the ongoing geopolitical conflict between Russia and Ukraine. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the current COVID-19 pandemic, political disruption or other geopolitical events, including an expansion of the conflict between Russia and Ukraine or instigation of other military conflicts, could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

Our principal office is located at 1601 Trapelo Road, Suite 178, Waltham, MA, 02451, where we lease 9,600 square feet of office space for general and administrative purposes. We lease this space under a lease agreement that terminates on September 30, 2026.

Item 3. Legal Proceedings.

We are not currently party to any material legal proceedings. From time to time, we may become involved in litigation or legal proceedings relating to claims arising from the ordinary course of business.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock has been listed on the Nasdaq Global Market under the symbol "ADGI" since August 6, 2021. Prior to that time, there was no public market for our common stock.

Holders of Record

As of March 24, 2022, there were 42 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain all available funds and 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.

Recent Sales of Unregistered Securities

In April 2021, we issued and sold an aggregate of 4,296,550 shares of our Series C preferred stock to 36 investors at a purchase price of $78.08578 per share, for aggregate consideration of $335.5 million. The issuance of these securities was exempt from registration under Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D promulgated thereunder.

In April 2021, we issued and sold 1,000 shares of our common stock to one investor at a price of $15.88 per share, for consideration of $15,871. The issuance of these securities was exempt from registration under Section 4(a)(2) of the Securities Act and Rule 506(b) of Regulation D promulgated thereunder.

In May 2021, we issued 5,000 shares of our common stock to a consultant in exchange for services. The issuance of these securities was exempt from registration under Section 4(a)(2) of the Securities Act.

Use of Proceeds

On August 5, 2021, our Registration Statement on Form S-1, as amended (File No. 333-257975), was declared effective in connection with our initial public offering, pursuant to which we sold an aggregate of 20,930,000 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $17.00 per share. Morgan Stanley & Co. LLC, Jefferies LLC, Stifel, Nicolaus & Company, Incorporated and Guggenheim Securities, LLC acted as joint book-running managers.

The initial public offering closed on August 10, 2021. The aggregate net proceeds received by the Company from the IPO were approximately $327.5 million, after deducting underwriting discounts and commissions of $24.9 million and offering expenses payable by the Company of $3.4 million. In connection with our initial public offering, no payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates or to our affiliates. There has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on August 6, 2021.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Period	(a) Total Number of Shares (or Units) Purchased		b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 1, 2021 to October 31, 2021	—		—	—	—
November 1, 2021 to November 30, 2021	468,751	[1]	$ 0.002	—	—
December 1, 2021 to December 31, 2021	—		—	—	—
Total	468,751		$ 0.002	—	—

[1] We repurchased 468,751 shares of our common stock that were previously issued upon the early exercise of employee stock options in connection with the exercise of our repurchase right upon cessation of employment of certain of our employees.

Item 6. [Reserved]

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

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report, 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

Adagio Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of differentiated products for the prevention and treatment of infectious disease. We are developing our lead product candidate, adintrevimab, for the prevention and treatment of coronavirus disease 2019, or COVID-19, the disease caused by the virus SARS-CoV-2 and its variants. COVID-19 has caused the current global pandemic that remains a significant global health crisis and has resulted in millions of deaths and lasting health problems in many survivors. We believe that COVID-19 will become an endemic disease requiring a variety of effective, safe and convenient prevention and treatment options for years to come. We are leveraging our team's collective expertise and platform to deliver adintrevimab to patients and to discover novel solutions to infectious diseases through internal research and collaborations.

Adintrevimab is designed to be a potent, long-acting and broadly neutralizing antibody for both the prevention and treatment of COVID-19. We believe several key attributes combine to differentiate adintrevimab, including breadth, potency, durability of protection, convenient intramuscular, or IM, administration, and potential for broad application across multiple indications, depending on the SARS-CoV-2 variant.

Data from our Phase 1 healthy volunteer study ADG20-1-001 confirmed the extended half-life of adintrevimab, which we believe may allow for durable protection against COVID-19, depending on the variant. In February 2022, we expanded the Phase 1 study to evaluate safety and pharmacokinetics at higher doses. As of March 27, 2022, there were no study drug related adverse events, serious adverse events, injection-site reactions or hypersensitivity reactions reported across all dose levels evaluated.

We are assessing adintrevimab in two separate Phase 2/3 clinical trials: our EVADE trial to evaluate adintrevimab for the prevention of COVID-19 and our STAMP trial to evaluate adintrevimab for the treatment of COVID-19. Our EVADE clinical trial is a global Phase 2/3 clinical trial evaluating adintrevimab as a prevention for COVID-19 in both the post-exposure and pre-exposure settings. Our STAMP trial is our global Phase 2/3 clinical trial evaluating adintrevimab as a treatment for COVID-19. Due to the emergence and global spread of the Omicron variant, against which adintrevimab has reduced *in vitro* neutralization potency compared to prior variants, enrollment in both EVADE and STAMP was paused on January 11, 2022, and preliminary efficacy and safety data were evaluated in pre-and post-Omicron populations.

In the primary analysis population, patients infected with or exposed to a non-Omicron variant, or the pre-Omicron group, adintrevimab met the primary objectives across all three indications, demonstrating statistically significant and clinically meaningful efficacy. In pre-exposure and post-exposure prophylaxis, adintrevimab was associated with 71% and 75% relative risk reductions compared to placebo, respectively, in the prevention of RT-PCR confirmed symptomatic COVID-19. In an exploratory analysis of patients exposed to the Omicron variant, or the post-Omicron group, in pre-exposure prophylaxis, adintrevimab was associated with a clinically meaningful reduction in the risk of developing RT-PCR confirmed symptomatic COVID-19 compared with placebo. In treatment, adintrevimab was associated with a 66% relative risk reduction compared to placebo in the incidence COVID-19 related hospitalization or all cause death through Day 29 in the pre-Omicron group. In patients treated within three days of symptom onset, adintrevimab was associated with a reduced risk of COVID-19 hospitalization or death from any cause through Day 29 by 77% compared to placebo. A preliminary analysis of available safety data in each trial revealed a safety profile similar to that of placebo for adintrevimab.

We are also evaluating additional broadly neutralizing antibodies targeting the receptor binding domain, or RBD, as well as other subdomains within the spike protein for COVID-19. In addition, we plan to leverage the robust antibody discovery and development capabilities that have enabled our expedited advancement of adintrevimab into clinical trials to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza. In addition to building a portfolio of broadly neutralizing antibodies, we are leveraging our knowledge around broadly neutralizing antibody responses to inform the rational design of coronavirus vaccine antigens.

SARS-CoV-2 has given rise to a global pandemic that swept rapidly throughout the world in 2020. Of significant current concern is the continued emergence of a number of SARS-CoV-2 variants with increased transmissibility, pathogenicity, and/or the ability to evade neutralizing antibodies. In addition to the emergence of these variants, there are multiple factors that we

believe contribute to the likelihood of COVID-19 becoming an endemic threat, including: (1) viral transmission before symptom onset; (2) uneven global rollout of vaccinations; (3) ongoing vaccine hesitancy; (4) limited duration of immunity conferred by both natural infection and vaccination; (5) limited vaccine efficacy against certain SARS-CoV-2 variants; (6) uncertain impact of vaccines on transmission; and (7) variable implementation of virus mitigation behaviors, such as wearing masks and social distancing. We also believe that future pandemics similar to the COVID-19 pandemic are likely because, in many parts of the world, humans live in close proximity to animal species harboring coronaviruses that are capable of infecting humans.

Our vision is to discover, develop and commercialize differentiated products for the prevention and treatment of infectious diseases. To enable this vision, our current discovery efforts are focused on unique antibody-based product candidates that we optimize to improve breadth, potency, half-life, where applicable, and developability. Key elements that we believe differentiate our approach include: (1) recognition of the importance of and identification of broadly neutralizing antibodies; (2) industry-leading B cell mining, protein engineering and developability screening capabilities through our internal expertise and collaborations; and (3) reducing risk of clinical resistance.

We were formed in June 2020. In July 2020, we entered into an assignment and license agreement, or the Adimab Assignment Agreement, with Adimab, pursuant to which we acquired certain rights to Adimab's antibodies relating to COVID-19 and severe acute respiratory syndrome, or SARS, as well as related provisional patent applications, know-how and data generated with respect to the associated antibodies. In addition, Adimab granted to us a non-exclusive, worldwide license to certain of Adimab's platform patents and technology for use in research and development. In connection with the rights and license acquired, we issued 5,000,000 shares of our Series A preferred stock to Adimab. In May 2021, we entered into a funded discovery agreement with Adimab focused on discovery efforts for new antibodies that may be effective against other coronaviruses and influenza, both of which have the potential to cause pandemics. In the event that Adimab discovers an antibody that is expected to meet certain product profiles developed by Adagio, Adagio will have the exclusive option to require Adimab to assign us its rights in any such antibody and to grant us certain licenses. In addition, the Company engages third parties, including The Scripps Research Institute, or TSRI, to perform ongoing research and development and other services on its behalf.

Since our inception, we have devoted substantially all of our resources to organizing and staffing, building an intellectual property portfolio, business planning, conducting research and development, establishing and executing arrangements with third parties for the manufacture of our product candidates and raising capital. We rely heavily on external consultants and contract research organizations, or CROs, to conduct our non-clinical, preclinical and clinical activities. Additionally, we are currently dependent on WuXi Biologics (Hong Kong) Limited, or WuXi, a contract development and manufacturing organization, or CDMO, for the manufacture of our product candidates for clinical and commercial use. We expect to continue to rely on third parties for clinical trials and the manufacture and testing of our product candidates.

Since our inception, we have financed our operations with net proceeds of $464.7 million from sales of our preferred stock, and most recently, with net proceeds from our initial public offering, or IPO. In August 2021, we completed our IPO, pursuant to which we issued and sold 20,930,000 shares of our common stock, including 2,730,000 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds from our IPO of $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us. To date, we have not generated any revenue from any sources, including product sales. We have not yet commenced significant development activities with respect to other product candidates. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our product candidates, if approved.

Since our inception, we have incurred significant losses, including net losses of $226.8 million and $65.3 million for the year ended December 31, 2021 and the period from June 3, 2020 (inception) to December 31, 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $292.1 million. We expect to continue to incur significant expenses and recognize losses in the foreseeable future as we expand and progress our research and development activities as well as the associated manufacturing activities and commercialization efforts. In addition, our losses from operations may fluctuate significantly from period to period depending on the timing of our clinical trials and our expenditures on other research and development activities, including any associated manufacturing activities, and potential commercialization efforts. We anticipate that our expenses will increase substantially in connection with our ongoing activities, as we:

- continue to conduct our ongoing clinical trials of adintrevimab, including advancement through late-stage global clinical trials, as well as initiate and complete additional clinical trials of future product candidates or current product candidates in new indications or patient populations;

- continue to advance the preclinical development of our other product candidates and our preclinical and discovery programs;
- seek regulatory approval for any product candidates that successfully complete clinical trials;
- pursue marketing approvals or EUA and reimbursement for our product candidates;
- acquire or in-license other product candidates, intellectual property and/or technologies;
- develop, establish and validate our commercial-scale current good manufacturing practices, or cGMP, manufacturing process;
- manufacture material under cGMP for clinical trials and potential EUA and commercial sales at our contracted manufacturing facilities;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;
- establish a sales, marketing and distribution infrastructure and scale up manufacturing capabilities to commercialize any product candidates for which we may obtain regulatory approval or EUA;
- hire and retain additional personnel, including research, clinical, development, manufacturing, quality control, quality assurance, regulatory and scientific personnel;
- add operational, financial, corporate development, management information systems and administrative personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

We do not anticipate generating revenue from product sales, including government supply contracts, unless and until we successfully complete clinical development and obtain marketing approvals or EUA for one or more of our product candidates. We are currently establishing our commercial infrastructure to support the anticipated marketing and distribution of our product candidates. Subject to receiving marketing approval or EUA for any of our product candidates for the prevention and/or treatment of COVID-19, we expect to enter into arrangements with third parties for the sale, marketing and distribution of our product candidates. Accordingly, if we obtain marketing approval or EUA for any of our product candidates, we will incur significant additional commercialization expenses related to product manufacturing, marketing, sales and distribution.

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 a combination of equity offerings, government or private-party grants, debt financings, collaborations with other companies and strategic alliances. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. We may never obtain regulatory approval for any of our product candidates. Even if we are able to generate product sales, we may not become profitable. 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 at planned levels and be forced to reduce or terminate our operations.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities of $591.4 million as of December 31, 2021, will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2024. 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."

Impact of COVID-19 on Our Operations

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. The evolving and constantly changing impact of the pandemic will directly affect the potential commercial prospects of adintrevimab for the prevention and treatment of COVID-19. The severity of the COVID-19 pandemic and the continued emergence of variants of

concern (such as the widespread Omicron and Delta variants), the availability, administration and acceptance of vaccines, monoclonal antibodies, antiviral agents and other therapeutic modalities, the introduction of local, national and/or employer vaccine mandates, and the potential development of "herd immunity" by the global population will affect the design and enrollment of our clinical trials, the potential regulatory authorization or approval of our product candidates and the commercialization of our product candidates, if approved.

In addition, our business and operations may be more broadly adversely affected by the COVID-19 pandemic. The COVID-19 outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen. The global COVID-19 pandemic continues to evolve rapidly, and we will continue to monitor it closely. The ultimate extent of the impact of the COVID-19 pandemic on our business, financial condition, operations and product development timelines and plans remains highly uncertain and will depend on future developments, including the duration and spread of outbreaks and the continued emergence of variants, its impact on our clinical trial design and enrollment, trial sites, contract research organizations, or CROs, contract development and manufacturing organizations, or CDMOs, and other third parties with which we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. To date, we have experienced some delays and disruptions in our development activities as a result of the COVID-19 pandemic. Some of our CROs, CDMOs and other service providers also continue to be impacted. We will continue to monitor developments as we address the disruptions, delays and uncertainties relating to the COVID-19 pandemic. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, our results and operations may be materially adversely affected and may affect our ability to raise capital.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from product sales, including government supply contracts, or any other sources. If our development efforts for our product candidates are successful and result in regulatory approval or collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments from collaboration or license agreements that we may enter into with third parties, or any combination thereof.

Research and Development Expenses

The nature of our business and primary focus of our activities generate a significant amount of research and development costs. Research and development expenses represent costs incurred by us for:

- the non-clinical and preclinical development of our product candidates, including our discovery efforts;
- the procurement of our product candidates from third-party manufacturers; and
- the global clinical development of our product candidates

Such costs consist of:

- personnel-related expenses, including salaries, bonuses, benefits and other compensation-related costs, including stock-based compensation expense, for employees engaged in research and development functions;
- expenses incurred under agreements with third parties, such as consultants, contractors and CROs, that conduct the non-clinical and preclinical studies and clinical trials of our product candidates and research programs;
- costs of procuring manufactured product candidates for use in non-clinical studies, preclinical studies and clinical trials from third-party CDMOs;
- costs of outside consultants and advisors, including their fees and stock-based compensation;
- payments made under third-party licensing agreements; and
- other expenses incurred as a result of research and development activities.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Our primary focus since inception has been the development of adintrevimab. Our research and development costs consist primarily of external costs, such as fees paid to CDMOs, CROs and consultants in connection with our non-clinical studies, preclinical studies and clinical trials. To date, external research and development costs for any individual product candidate have been tracked commencing upon product candidate nomination. We do not allocate employee-related costs, costs associated with our discovery efforts and other internal or indirect costs to specific research and development programs or product candidates because these resources are used and these costs are deployed across multiple programs under development and, as such, are not separately classified.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher and more variable development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will increase substantially in the near term as we advance adintrevimab through clinical development on a global basis, pursue regulatory approval of adintrevimab, continue to discover and develop additional product candidates and incur expenses associated with hiring additional personnel to support our research and development efforts, including the associated manufacturing activities.

At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of any of our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from sales or licensing of our product candidates. This is due to the numerous risks and uncertainties associated with drug development, including the uncertainty of:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- filing acceptable investigational new drug applications with the U.S. Food and Drug Administration or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials, manufacture the product candidates and complete associated regulatory activities;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and successfully develop, obtain regulatory approval or EUA for our product candidates;
- successful enrollment and timely completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- the costs associated with the development of any additional development programs and product candidates we identify in-house or acquire through collaborations;
- the prevalence, nature and severity of adverse events experienced with adintrevimab or any other product candidates;
- the terms and timing of any collaboration, license or other arrangement, including the terms and timing of any milestone payments thereunder;
- our ability to obtain and maintain patent, trademark and trade secret protection and regulatory exclusivity for our product candidates, if and when approved, and otherwise protecting our rights in our intellectual property portfolio;
- receipt of timely marketing approvals from applicable regulatory authorities;
- our ability to maintain compliance with regulatory requirements, including good clinical practices, current good laboratory practices and cGMPs, and to comply effectively with other rules, regulations and procedures applicable to the development and sale of pharmaceutical products;
- potential significant and changing government regulation, regulatory guidance and requirements and evolving treatment guidelines; and

- the impact of any business interruptions to our operations or those of third parties with which we work, particularly in light of the current COVID-19 pandemic.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. We may never succeed in obtaining regulatory approval or EUA for any of our product candidates. In addition, in the absence of a public health emergency, we will not be able to receive an EUA. The national public health emergency declaration was most recently renewed in January 2022 and may or may not be renewed again.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development, or IPR&D, expenses consist primarily of the upfront costs we incurred in July 2020, as well as any costs of contingent milestone payments we incurred in subsequent periods, to acquire rights to Adimab's antibodies relating to COVID-19 and SARS and related intellectual property and a license to certain of Adimab's platform patents and technology, or the IPR&D assets, for use in the research and development of our product candidates. We expensed the cost of the IPR&D assets because they had no alternative future use as of the acquisition date. We will recognize additional acquired IPR&D expenses in the future if and when we become obligated to make contingent milestone payments to Adimab under the terms of the agreement by which we acquired the IPR&D assets.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, bonuses, benefits, third-party fees and other related costs, including stock-based compensation, for our personnel and external contractors involved in our executive, finance, legal, business development and other administrative functions as well as our commercial function. Selling, general and administrative expenses also include costs incurred for outside services associated with such functions, including legal fees relating to patent and corporate matters; professional fees for accounting, auditing, tax and administrative consulting services; insurance costs; market research costs; and other selling, general and administrative expenses. These costs relate to the operation of the business, unrelated to the research and development function, or any individual program.

We anticipate that our selling, general and administrative expenses will increase substantially in the future as our business expands and we increase our headcount to support the expected growth in our research and development activities and the potential commercialization of our product candidates. In particular, we expect to incur additional commercialization expenses prior to any regulatory approval or EUA of our product candidates as we continue to expand our commercial function to support potential future product launches. We also anticipate that we will incur increased expenses associated with operating as a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services, director and officer insurance premiums, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file additional patent applications to protect innovations arising from our research and development activities.

Through December 31, 2021, we have operated as a virtual company and maintain a corporate headquarters for general and administrative purposes only. Therefore, we do not incur material operating expenses for the rent, maintenance and insurance of facilities or for depreciation of fixed assets.

Other Income (Expense), Net

Other income (expense), net consists of interest income earned from our cash, cash equivalents and marketable securities and the net amortization or accretion of premiums and discounts related to our marketable securities. We expect our interest income to vary each reporting period depending on our average bank deposits, money market funds and investment balances during the period and market interest rates.

Income Taxes

Since our inception, we have not recorded any income tax expense or realized benefits for the net losses we have incurred or for the research and development tax credits generated in each period as we believe, based upon the weight of available evidence, that it is more likely than not that all of our net operating loss, or NOL, carryforwards and tax credit carryforwards will not be realized.

Results of Operations

Comparison of the Year Ended December 31, 2021 and the Period from June 3, 2020 (Inception) to December 31, 2020

The following table summarizes our results of operations for the year ended December 31, 2021 and the period from June 3, 2020 (inception) to December 31, 2020. We were formed in June 2020 and, accordingly, our results of operations for the period from June 3, 2020 (inception) to December 31, 2020 are not comparable to our results of operations for the year ended December 31, 2021.

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
	(in thousands)	
Operating expenses:		
Research and development	$ 182,891	$ 21,992
Acquired in-process research and development	7,500	40,125
Selling, general and administrative	36,517	3,210
Total operating expenses	226,908	65,327
Loss from operations	(226,908)	(65,327)
Other income (expense):		
Other income (expense), net	118	8
Total other income (expense), net	118	8
Net loss	$ (226,790)	$ (65,319)

Research and Development Expenses

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
	(in thousands)	
Direct, external research and development expenses by program:		
Adintrevimab	$ 136,470	$ 18,523
ADG10[(1)]	10,881	—
Unallocated research and development expenses:		
Personnel related (including stock-based compensation)	23,470	1,743
External discovery-related costs and other	12,070	1,726
Total research and development expenses	$ 182,891	$ 21,992

[(1)] We have discontinued development of ADG10 due its less favorable neutralization profile compared to adintrevimab.

Research and development expenses were $182.9 million for the year ended December 31, 2021 and consisted primarily of the following:

- $77.2 million of clinical trial expenses related to start-up and ongoing activities for our clinical trials for the adintrevimab program;
- $58.8 million of contract development and manufacturing expenses related to the production of materials for use in our nonclinical studies and clinical trials for the adintrevimab and ADG10 programs, as well as supply for use under a potential EUA for adintrevimab, procured primarily from WuXi, our sole-source supplier of drug substance and drug product;
- $23.5 million of personnel-related costs, including salaries, bonuses and other compensation-related costs, including stock-based compensation of $6.6 million;
- $12.1 million of external discovery-related and other costs;
- $4.5 million of other external research and development costs associated with the adintrevimab program, including consulting services, insurance costs and software expenditures;

- $4.1 million of other contracted facility and product supply expenses related to services, storage, distribution and testing costs for the adintrevimab and ADG10 programs; and
- $2.7 million of non-clinical studies expenses associated with the adintrevimab program.

The contract manufacturing, clinical and other external research and development costs for our adintrevimab program were incurred in connection with our first-in-human Phase 1 clinical trial to evaluate adintrevimab, our Phase 2/3 EVADE trial of adintrevimab for the prevention of COVID-19 and our Phase 2/3 STAMP trial of adintrevimab for the treatment of COVID-19.

Research and development expenses were $22.0 million for the period from June 30, 2020 (inception) to December 31, 2020 and consisted primarily of the following:

- $14.8 million of contract development and manufacturing expenses related to the production of materials for use in our preclinical studies and clinical trials for the adintrevimab program, procured primarily from WuXi, our sole-source supplier of drug substance;
- $1.4 million of clinical trial expenses related to start-up activities for our clinical trials for the adintrevimab program;
- $1.0 million of other external research and development costs associated with the adintrevimab program, including consulting services, insurance costs and software expenditures;
- $1.3 million of non-clinical studies expenses associated with the adintrevimab program;
- $1.7 million of personnel-related costs, including salaries, bonuses and other compensation-related costs, including stock-based compensation of $0.1 million; and
- $1.7 million of external discovery-related and other costs.

The contract manufacturing, clinical and other external research and development costs for our adintrevimab program were incurred in connection with our first-in-human Phase 1 clinical trial to evaluate adintrevimab and our Phase 2/3 STAMP trial of adintrevimab for the treatment of COVID-19.

Acquired In-Process Research and Development Expenses

Acquired IPR&D expenses of $7.5 million for the year ended December 31, 2021 consisted of the costs we incurred in the period under the Adimab Assignment Agreement for a $1.0 million milestone payment that became due to Adimab in February 2021 upon the dosing of the first patient in a Phase 1 clinical trial evaluating adintrevimab, a $2.5 million milestone payment that became due to Adimab in April 2021 upon the dosing of the first patient in the first Phase 2 clinical trial evaluating adintrevimab for the prevention of COVID-19, and a $4.0 million milestone payment that became due to Adimab in August 2021 upon dosing of the first patient in a Phase 3 clinical trial evaluating adintrevimab for the prevention of COVID-19. The second and third milestones were achieved in connection with our combined Phase 2/3 EVADE global clinical trial of adintrevimab for the prevention of COVID-19. We recognized the expense related to the first, second and third milestone payments in February, April and August 2021, respectively, when we deemed it probable that each specified milestone would be achieved. The amounts of these contingent payments were recognized as an IPR&D expense based on the nature, assessed as of each milestone achievement date, of the assets originally acquired from Adimab.

Acquired IPR&D expenses of $40.1 million for the year ended December 31, 2020 consisted primarily of the $39.9 million of costs we incurred in July 2020 to acquire rights to Adimab's antibodies relating to COVID-19 and SARS and related intellectual property and a license to certain of Adimab's platform patents and technology for use in the research and development of our product candidates.

Selling, General and Administrative Expenses

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
	(in thousands)	
Personnel related (including stock-based compensation)	$ 19,540	$ 1,239
Professional and consultant fees	15,563	1,849
Other	1,414	122
Total selling, general and administrative expenses	$ 36,517	$ 3,210

Selling, general and administrative expenses were $36.5 million for the year ended December 31, 2021 and consisted primarily of:

- $19.5 million of personnel-related costs, including salaries, bonuses and other compensation-related costs, including stock-based compensation of $11.2 million;
- $10.7 million of professional service fees, including corporate legal costs as well as costs related to intellectual property, legal and compliance costs;
- $2.5 million of market research costs relating to developing our potential commercialization plans and brand-related matters;
- $2.4 million of insurance costs; and
- $1.4 million related to non-capital software and hardware and other office-related expenses.

Selling, general and administrative expenses were $3.2 million for the period from June 30, 2020 (inception) to December 31, 2020 and consisted primarily of:

- $1.2 million of personnel-related costs, including salaries, bonuses and other compensation-related costs, including stock-based compensation of $30,000;
- $1.2 million of professional service fees, including corporate legal costs as well as costs related to intellectual property, legal and compliance costs;
- $0.6 million of market research costs relating to developing our potential commercialization plans and brand-related matters; and
- $0.1 million related to non-capital software and hardware and other office-related expenses.

Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2021 was $0.1 million, consisting primarily of $1.7 million of interest earned on our invested cash balances, partially offset by $1.4 million of net amortization of premiums related to our marketable securities.

Other income (expense), net for the year ended December 31, 2020 was less than $0.1 million, consisting of interest earned on our invested cash balances.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in June 2020, we have not generated any revenue from any sources, including from product sales, and have incurred significant operating losses and negative cash flows from operations. We expect to incur substantial expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. To date, we have financed our operations with net proceeds of $464.7 million from sales of our preferred stock, and most recently, with net proceeds from our IPO in August 2021, in which we issued and sold 20,930,000 shares of our common stock, including 2,730,000 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds from our IPO of $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

As of December 31, 2021, we had cash, cash equivalents and marketable securities of $591.4 million.

Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented:

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
	(in thousands)	
Net cash used in operating activities	$ (184,736)	$ (14,571)
Net cash used in investing activities	(50,711)	—
Net cash provided by financing activities	662,683	129,559
Net increase in cash and cash equivalents	$ 427,236	$ 114,988

Operating Activities

During the year ended December 31, 2021, operating activities used $184.7 million of cash, primarily due to our net loss of $226.8 million, partially offset by non-cash charges of $19.3 million and net cash provided by changes in our operating assets and liabilities of $22.8 million. Net cash provided by changes in our operating assets and liabilities consisted of a $51.3 million increase in accrued expenses, partially offset by a $22.9 million increase in prepaid expenses and other current assets, a $3.3 million increase in other non-current assets and a $2.4 million decrease in accounts payable. The increase in accrued expenses was primarily due to amounts owed to vendors in connection with our research and development activities, including increased external costs associated with clinical trials and manufacturing. The increase in prepaid expenses and other current assets and other non-current assets was primarily due to prepayments for external research and development activities and prepayments for insurance premiums. The decrease in accounts payable was primarily due to the timing of invoices received and payments made.

During the period from June 3, 2020 (inception) to December 31, 2020, operating activities used $14.6 million of cash, primarily due to our net loss of $65.3 million, partially offset by non-cash charges of $40.1 million and net cash provided by changes in our operating assets and liabilities of $10.7 million. Net cash provided by changes in our operating assets and liabilities consisted of an $8.2 million increase in accounts payable and a $4.9 million increase in accrued expenses, both partially offset by a $2.4 million increase in prepaid expenses and other current assets. The increases in accounts payable and accrued expenses were primarily due to amounts owed to vendors in connection with our research and development activities, including increased external costs associated with clinical trials and manufacturing, as well as increases in accrued employee bonuses. The increase in prepaid expenses and other current assets was primarily due to prepayments for external research and development activities.

Investing Activities

During the year ended December 31, 2021, net cash used in investing activities was $50.7 million, primarily related to purchases of marketable securities of $188.6 million, offset by maturities of marketable securities of $138.0 million.

We had no cash used in or provided by investing activities for the period from June 3, 2020 (inception) to December 31, 2020.

Financing Activities

During the year ended December 31, 2021, net cash provided by financing activities was $662.7 million, primarily related to net proceeds of $335.2 million from the issuance of our Series C preferred stock in April 2021 and net proceeds of $330.9 million from the issuance of our common stock in connection with our IPO in August 2021, offset by $3.4 million of payments of initial public offering costs.

During the period from June 3, 2020 (inception) to December 31, 2020, net cash provided by financing activities was $129.6 million, primarily related to net proceeds of $49.7 million from the issuance of our Series A preferred stock in July 2020 and net proceeds of $79.8 million from the issuance of our Series B preferred stock in October and November 2020.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the non-clinical and preclinical studies and the current and future clinical trials of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including:

- the rate of progress in the development of adintrevimab and our other product candidates;
- the scope, progress, results and costs of non-clinical studies, preclinical development, laboratory testing and clinical trials for adintrevimab and future product candidates and associated development programs;
- the extent to which we develop, in-license or acquire other product candidates and technologies in our pipeline;
- the scope, progress, results and costs as well as timing of process development and manufacturing scale-up and validation activities associated with adintrevimab and our future product candidates and other programs as we advance them through preclinical and clinical development;
- the number and development requirements of product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- our headcount growth and associated costs as we expand our research and development capabilities and establish a commercial infrastructure;
- the timing and costs of securing sufficient capacity for commercial supply of our product candidates, or the raw material components thereof;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval or EUA;
- the costs necessary to obtain regulatory approvals, if any, for products in the United States and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the continuation of our existing licensing and collaboration arrangements and entry into new collaborations and licensing arrangements, if at all;
- the need and ability to hire additional research, clinical, development, scientific and manufacturing personnel;
- the costs we incur in maintaining business operations;
- the need to implement additional internal systems and infrastructure;
- the effect of competing technological, product and market developments;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs of operating as a public company; and
- the progression of the COVID-19 pandemic and emergence of potential outbreaks of other coronaviruses, including the impact of any business interruptions to our operations or to those of our contract manufacturers, suppliers or other vendors resulting from the COVID-19 pandemic or other similar public health crises.

We believe that our cash, cash equivalents and marketable securities, will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2024. 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.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, government or private-party grants, debt financings, collaborations, strategic 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 of such securities may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a common stockholder. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions,

such as incurring debt, making acquisitions or capital expenditures or declaring dividends, which could adversely constrain our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing 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. If we are unable to raise additional funds through equity or debt financings or through other sources, when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2021 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
Commercial manufacturing agreement[1]	$ 139,544	$ 75,599	$ 63,945	$ —	$ —
Lease obligations[2]	1,991	401	1,262	328	—
Total contractual cash obligations	$ 141,535	$ 76,000	$ 65,207	$ 328	$ —

(1) Amounts represent minimum purchase commitments under an arrangement with our CDMO for commercial supply. The table reflects obligations that are non-cancelable as of December 31, 2021, based on the expected due dates for such purchases.

(2) Amounts represent minimum payments due under our operating lease agreement for office space in Waltham, Massachusetts, which expires in 2026 with an option to terminate in 2023.

In December 2020, we entered into a Commercial Manufacturing Services Agreement with WuXi, which was amended and restated in August 2021 (as amended and restated, the Commercial Manufacturing Agreement). The Commercial Manufacturing Agreement outlines the terms and conditions under which WuXi will manufacture adintrevimab drug substance and drug product for commercial use. Our requirements for manufacture of adintrevimab for the year ending December 31, 2022, the payments for which will extend into 2023, are governed by a binding, forecasted schedule and are presented in the preceding table.

In September 2021, we entered into a five-year lease agreement for approximately 9,600 square feet of office space in Waltham, Massachusetts. The monthly rental payments under the lease agreement, which include base rent charges of approximately $0.4 million per year, are subject to periodic rent increases through September 2026.

Under a separate cell line license agreement with WuXi, as of December 31, 2020, we were obligated to pay a license fee of $0.2 million to WuXi, which was an accrued expense as of December 31, 2020 and paid during the year ended December 31, 2021. Under the agreement, we are obligated to pay royalties in the range of 0.3% to 0.5% to WuXi based on our net sales of any products covered by the license. However, if we use WuXi to manufacture all of our commercial supplies, no royalties would be owed by us to WuXi for net sales of licensed products. We have an option to buy out our royalty obligations by making a one-time payment of $15.0 million to WuXi. These royalty payments are not included in the preceding table as the amount and timing of such payments are not known.

In July 2020, we entered into an assignment and license agreement with Adimab, or the Adimab Assignment Agreement, with respect to discovery and optimization of coronavirus-specific antibodies, including COVID-19 and SARS. Under the Adimab Assignment Agreement, we are obligated to pay Adimab up to $16.5 million upon the achievement of specified development and regulatory milestones for the first product licensed under the agreement that achieves specified development and regulatory events and up to $8.1 million upon the achievement of specified development and regulatory milestones for the second product licensed under the agreement that achieves such development and regulatory events. In February 2021, we achieved the first specified milestone under the agreement upon dosing of the first patient in a Phase 1 global clinical trial evaluating adintrevimab, which obligated us to make a $1.0 million payment to Adimab. We made the payment in March 2021. In April 2021, we achieved the second specified milestone under the agreement upon dosing of the first patient in a Phase 2 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated us to make a $2.5 million payment to Adimab. We made the payment in June 2021. In August 2021, we achieved the third specified milestone under the agreement upon dosing of the first patient in a Phase 3 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated us to make a $4.0 million milestone payment to Adimab. The next potential milestone under the

Adimab Assignment Agreement is a $4.0 million milestone related to the acceptance of the filing of the first New Drug Application for a product licensed under the agreement by the FDA. In addition, we are obligated to pay Adimab royalties of a mid single-digit percentage based on our net sales of any products covered by the rights assigned. Further, we are obligated to pay Adimab royalties of a specified percentage in the range of 45% to 55% of any compulsory sublicense consideration received by us in lieu of certain royalty payments. These milestone and royalty payments are not included in the preceding table as the amount and timing of such payments are not known. For additional information, see to Note 7 to our annual consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

In May 2021, we entered into a collaboration agreement with Adimab, or the Adimab Collaboration Agreement, for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Collaboration Agreement, we and Adimab will collaborate on research programs for a specified number of targets selected by us within a specified time period. Under the agreement, we are obligated to pay Adimab a quarterly fee of $1.3 million, in exchange for Adimab and its affiliates agreeing not to assist or direct certain third parties to discover or optimize antibodies that are intended to bind to coronaviruses or influenza viruses, which obligation may be cancelled at our option at any time. For each agreed upon research program that is commenced, we are obligated to pay Adimab quarterly for its services performed during a given research program at a specified full-time equivalent rate; a discovery delivery fee of $0.2 million; and an optimization completion fee of $0.2 million. For each option exercised by us to commercialize a specific research program, we are obligated to pay Adimab an exercise fee of $1.0 million. Under the Adimab Collaboration Agreement, we are obligated to pay Adimab up to $18.0 million upon the achievement of specified development and regulatory milestones for each product under the agreement that achieves such milestones. We are also obligated to pay Adimab royalties of a mid single-digit percentage based on annual aggregate worldwide net sales of products, subject to reductions for third-party licenses. In addition, we are obligated to pay Adimab for Adimab's performance of certain validation work with respect to certain antigens acquired from a third party. In consideration for this work, we are obligated to pay Adimab royalties of a low single-digit percentage based on annual aggregate worldwide net sales of products that contain such antigens for the same royalty term as antibody-based products, but we are not obligated to make any milestone payments for such antigen products. These milestone and royalty payments are not included in the preceding table as the amount and timing of such payments are not known. For additional information, see to Note 7 to our annual consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

In August 2021, we entered into a research collaboration and license agreement, or the Research Agreement, with The Scripps Research Institute, or TSRI. Under the terms of the Research Agreement, TSRI will perform research activities to identify vaccine candidates for the prevention, diagnosis or treatment of influenza or beta coronaviruses, or the Research Program. The Company is obligated to provide the research funding necessary to carry out each activity initiated under the Research Program pursuant to a budget to be agreed upon by the parties. In August 2021, the Company paid TSRI $1.5 million in funding, which was credited against research funding payable by the Company under the Research Agreement. Additionally, the Company is obligated to make specified payments to TSRI to the extent that TSRI complies with certain exclusivity covenants. To the extent any product licensed under the Research Agreement is commercialized, the Company is obligated to pay TSRI royalties of a low single-digit percentage on a licensed product-by-licensed product and country-by-country basis based on a percentage of net sales, subject to reduction and floor. Royalties are payable for each product on a country-by-country basis through the later of (i) the expiration of the last valid claim of any patent covering such product in such country or (ii) 12 years from the first commercial sale of such product. The Research Agreement will expire when no further royalties are due to TSRI. For additional information, see to Note 7 to our annual consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

We enter into other contracts in the normal course of business with CROs, contract manufacturing organizations and other third parties for preclinical research studies and testing, clinical trials, manufacturing and other services. These contracts do not contain any minimum purchase commitments and provide for termination by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation, including non-cancelable obligations of our service providers and, in some cases, wind-down costs. The exact amounts of such obligations are dependent on the timing of termination and the terms of the associated agreement. Accordingly, these payments are not included in the preceding table as the amount and timing of such payments are not known.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, and liabilities and the disclosure of contingent assets and liabilities at

the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our 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 value of assets and liabilities and recorded amounts of expenses 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 consolidated financial statements appearing at the end of this Annual Report, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

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. This process involves estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advance payments. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. At each end period, we corroborate the accuracy of these estimates with the service providers and make adjustments, if necessary. Examples of estimated accrued research and development expenses include those related to fees paid to:

- CROs in connection with performing non-clinical studies, preclinical studies and clinical trials;
- CDMOs related to the production of our product candidates for non-clinical studies, preclinical studies and clinical trials; and
- other providers and vendors in connection with research and development activities.

We record the expense and accrual related to contract research and manufacturing based on our estimates of the services received and efforts expended considering a number of factors, including our knowledge of the progress towards completion of the research, development and manufacturing activities; invoicing to date under the contracts; communication from the CROs, CDMOs and other companies of any actual costs incurred during the period that have not yet been invoiced; and the costs included in the contracts and purchase orders. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. For CRO expense and accruals, there is estimation uncertainty related to the timing of submission of investigator fees for the period. For CDMO expense and accruals, there is estimation uncertainty related to the percentage of completion of in process batch manufacturing at period end. To date, we have not had significant changes to our estimates. 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 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 the estimate, we adjust the accrual or the amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Asset Acquisitions and Acquired In-Process Research and Development Expenses

We measure and recognize asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire IPR&D with no alternative future use is recognized as expense on the acquisition date.

Contingent consideration in asset acquisitions payable in the form of cash is recognized in the period the triggering event is determined to be probable of occurrence and the related amount is reasonably estimable. Such amounts are expensed or capitalized based on the nature of the associated asset at the date the related contingency is resolved.

We concluded that the agreement under which we acquired rights to Adimab's antibodies relating to COVID-19 and SARS and related intellectual property and a license to certain of Adimab's platform patents and technology in June 2020 represented an asset acquisition of IPR&D assets with no alternative future use. We further concluded that the arrangement did

not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset.

Determination of Fair Value of Common Stock

Prior to the initial public offering, as there was no public market for our common stock, the estimated fair value of our common stock underlying our stock-based awards was determined by our board of directors as of each option grant date with input from management, considering our most recently available third-party valuations of common stock and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were prepared 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. Our common stock valuations were prepared using either a current value method, or CVM, an option pricing method, or OPM, or a hybrid method. To estimate our enterprise value, the CVM used an asset approach and the OPM and hybrid methods used a market approach. Under the CVM, once the fair value of the enterprise is established based on the balance sheet, the value is allocated to the various series of preferred and common stock based on their respective liquidation preferences or conversion values, whichever is greater. 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 has 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. The hybrid method is a probability-weighted expected return method, or PWERM, where the equity value in one or more of the 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. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock.

Prior to the initial public offering, these third-party valuations were performed at various dates. In addition to considering the results of these third-party valuations, our board of directors considered various objective and subjective factors to determine the fair value of common stock as of each grant date, including:

- the prices at which we sold our preferred stock and the superior rights and preferences of our preferred stock relative to those of our common stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and clinical trials for our product candidates;
- our stage of development and our business strategy;
- external market conditions affecting the biotechnology industry and trends within the biotechnology industry;
- the competitive landscape for similar products for the treatment and prevention of COVID-19;
- our financial position, including cash on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock;
- the likelihood of achieving a liquidity event, such as an initial public offering, or 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.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management's judgment. As a result, if we had used significantly different assumptions or estimates, the fair value of our common stock and our stock-based compensation expense could be materially different.

Stock-Based Compensation

We grant stock-based awards to employees, directors and non-employees in the form of stock options to purchase shares of our common stock. We measure stock options with service-based vesting granted to employees, directors and non-employees

based on the fair value on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield. After the initial public offering, the fair value of our common stock is based on the quoted market price of our common stock. Due to the proximity to the IPO, we continue to lack company-specific historical and implied volatility information. Therefore, we estimate our expected stock volatility based on the historical volatility of a publicly traded set of peer companies and we expect to continue to do so until such time that we have adequate historical data regarding the volatility of our own traded stock price. We have issued awards with only service-based vesting conditions through December 31, 2021. Compensation expense for awards granted to employees and directors for their service on the board of directors is recognized on a straight-line basis over the requisite service period of the respective award, which is generally the vesting period of the award. Compensation expense for awards granted to non-employees is recognized in the same period and manner as if we had paid cash for the goods or services provided, which is generally the vesting period of the award. We account for forfeitures of stock-based awards as they occur.

In future periods, we expect stock-based compensation expense to increase due to our existing unrecognized stock-based compensation expense and to additional stock-based awards we expect to grant to continue to attract new hires and retain our existing employees.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations and cash flows is disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to “opt out” of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised 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. We may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15, Exhibit and Financial Statement Schedules, of this Annual Report on Form 10-K.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Interim Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Based on that evaluation of our disclosure controls and procedures as of December 31, 2021, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) or an attestation report of our independent registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

Remediation of Previously Reported Material Weakness in Internal Control Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

We previously identified and disclosed a material weakness in our internal control over financial reporting regarding the following:

We did not design and maintain effective controls over the completeness and accuracy of research and development expenses, prepaid expenses, accounts payable and accrued expenses related to our contract manufacturing agreements during interim financial reporting periods. This material weakness resulted in adjustments to research and development expenses for the three months ended March 31, 2021, and prepaid expenses, accounts payable and accrued expenses as of March 31, 2021, all of which were recorded prior to the issuance of our interim condensed consolidated financial statements.

During the third quarter of 2021, we designed and implemented controls to remediate the material weakness, including strengthening and formalizing our documentation of policies and further evolving our accounting processes and post-closing review procedures related to the completeness and accuracy of research and development expenses, prepaid expenses, accounts payable and accrued expenses of our contract manufacturing agreements.

These controls around our oversight and review of the completeness and accuracy of research and development expenses, prepaid expenses, accounts payable and accrued expenses of our contract manufacturing agreements have operated for a sufficient period of time and our management has concluded, based on evidence obtained in validating the design and operating effectiveness of the controls, that the efforts undertaken to enhance the design of our controls over the completeness and accuracy of research and development expenses, prepaid expenses, accounts payable and accrued expenses related to our contract manufacturing agreements, which were implemented and executed in 2021, would lead to the prevention or detection of a material misstatement of our consolidated financial statements. As such, our management concluded that we have remediated this material weakness as of December 31, 2021.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

On March 25, 2022, we entered into amendments to the employment agreements for each of David Hering, M.B.A., our Interim Chief Executive Officer and Chief Operating Officer, and Jane Pritchett Henderson, our Chief Financial Officer and Chief Business Officer. Such amendments reflect the increased compensation approved by our board of directors as described in our Current Report on Form 8-K/A filed on March 21, 2022 and Current Report on Form 8-K filed on March 21, 2022, respectively, which are incorporated herein by reference.

The foregoing description of the amendments to these employment agreements is only a summary and is qualified in its entirety by reference to the complete terms and conditions of the amendments, which are filed as Exhibit 10.10 and Exhibit 10.12 to this Annual Report on Form 10-K and incorporated herein by reference.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 (other than as set forth below) will be included in the sections captioned "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," and "Executive Officers" in our definitive proxy statement to be filed with the Securities and Exchange Commission (the "SEC") with respect to our 2022 Annual Meeting of Stockholders within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates, or the Proxy Statement, which information is incorporated herein by reference.

We have adopted a Code of Business Ethics and Conduct within the meaning of Item 406(b) of Regulation S-K. This Code of Business Ethics and Conduct 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, and is posted in the "Corporate Governance" sub-section of the "Investors & Media" section (https://investors.adagiotx.com/) of our corporate website https://adagiotx.com/. We intend to disclose on our website any amendments to, or waivers from, the Code of Business Ethics and Conduct that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in the sections captioned "Executive Compensation" and "Director Compensation" in our Proxy Statement, which information is incorporated herein by reference.

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

The information required by this Item 12 will be included in the sections captioned "Securities Authorized for Issuance under Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management" in our Proxy Statement, which information is incorporated herein by reference.

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

The information required by this Item 13 will be included in the sections captioned "Transactions with Related Persons and Indemnification" and "Independence of the Board of Directors" in our Proxy Statement, which information is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in the section captioned "Ratification of Selection of Independent Registered Public Accounting Firm" in our Proxy Statement, which information is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a)(1) For a list of the financial statements filed as part of this Annual Report on Form 10-K, see Index to Consolidated Financial Statements on page F-1 of this Annual Report on Form 10-K, incorporated into this Item by reference.

(a)(2) Financial statement schedules have been omitted because they are either not required or not applicable or the information is included in the consolidated financial statements or the notes thereto.

(a)(3) Exhibits:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on August 10, 2021).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on August 10, 2021).
4.1	Second Amended and Restated Investors' Rights Agreement, by and among the Company and certain of its stockholders, dated April 16, 2021 (incorporated by reference to Exhibit 4.1 of the Company's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
4.2*	Description of Adagio Therapeutics, Inc. Common Stock.
10.1+	2020 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Stock Option Grant and Notice of Exercise (incorporated by reference to Exhibit 10.1 of the Company's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
10.2+	2021 Equity Incentive Plan and Forms of Option Grant Notice and Agreement, Exercise Notice, Early Exercise Notice and Restricted Stock Award Notice (incorporated by reference to Exhibit 10.2 of the Company's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on August 2, 2021).
10.3+	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 of the Company's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on August 2, 2021).
10.4+	Form of Indemnification Agreement with Executive Officers and Directors (incorporated by reference to Exhibit 10.4 of the Company's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on August 2, 2021).
10.5*+	Non-Employee Director Compensation Policy.
10.6+	Employment Agreement by and between the Registrant and Tillman U. Gerngross, dated August 5, 2021 (incorporated by reference to Exhibit 10.5 of the Company's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on September 20, 2021).
10.7+	Amended and Restated Employment Agreement by and between the Registrant and Lynn Connolly, dated August 5, 2021 (incorporated by reference to Exhibit 10.6 of the Company's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on September 20, 2021).
10.8+	Amended and Restated Employment Agreement by and between the Registrant and Rebecca Dabora, dated August 5, 2021(incorporated by reference to Exhibit 10.7 of the Company's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on September 20, 2021).
10.9+	Amended and Restated Employment Agreement by and between the Registrant and David Hering, dated August 5, 2021 (incorporated by reference to Exhibit 99.1 of the Company's Current Report on Form 8-K/A (File No. 001-40703), filed with the Securities and Exchange Commission on March 21, 2022).
10.10*+	First Amendment to the Amended and Restated Employment Agreement of David Hering by and between the Registrant and David Hering, dated February 23, 2022.
10.11*+	Employment Agreement by and between the Registrant and Jill Andersen, dated September 24, 2021.
10.12*+	First Amendment to the Amended and Restated Employment Agreement of Jane Henderson by and between the Registrant and Jane Pritchett Henderson, dated March 18, 2022.

10.13+	Form of Executive Officer Employment Agreement (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on November 15, 2021).
10.14†#	Assignment and License Agreement by and between the Registrant and Adimab, LLC, dated July 8, 2020 (incorporated by reference to Exhibit 10.5 of the Company's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
10.15†#	Collaboration Agreement by and between the Company and Adimab, LLC, dated May 21, 2021 (incorporated by reference to Exhibit 10.6 of the Company's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
10.16†#	Amended and Restated Commercial Manufacturing Services Agreement by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated August 12, 2021 (incorporated by reference to Exhibit 10.2 of the Company's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on November 15, 2021).
10.17†#	Cell Line License Agreement by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated December 2, 2020 (incorporated by reference to Exhibit 10.8 of the Company's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
21.1	Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 of the Company's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney (included on signature page)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*^	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*^	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

+ Indicates management contract or compensatory plan.

† Certain portions of this exhibit (indicated by asterisks) have been omitted because they are not material and are the type that the Registrant treats as private or confidential.

Certain schedules to this agreement have been omitted in accordance with Item 601(b)(2) of Regulation S-K. A copy of any omitted schedules will be furnished supplementally to the SEC upon request.

^ These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

ADAGIO THERAPEUTICS, INC.

Date: March 31, 2022

By: /s/ David Hering, M.B.A.
David Hering, M.B.A.
Interim Chief Executive Officer and Chief Operating Officer

/s/ Jane Pritchett Henderson
Jane Pritchett Henderson
Chief Financial Officer and Chief Business Officer

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints David Hering, M.B.A. and Jane Pritchett Henderson, and each of them, as his or her true and lawful agents, proxies and attorneys-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Adagio Therapeutics, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his, her or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Name	Title	Date
/s/ David Hering, M.B.A.	Interim Chief Executive Officer and Chief Operating Officer	March 31, 2022
David Hering, M.B.A.	*(Principal Executive Officer)*	
/s/ Jane Pritchett Henderson	Chief Financial Officer and Chief Business Officer	March 31, 2022
Jane Pritchett Henderson	*(Principal Financial Officer and Principal Accounting Officer)*	
/s/ René Russo, Pharm.D.	Co-Founder, Director and Chair of the Board	March 31, 2022
René Russo, Pharm.D.		
/s/ Terrance McGuire	Director	March 31, 2022
Terrance McGuire		
	Director	
Ajay Royan		
/s/ Howard Mayer, M.D.	Director	March 31, 2022
Howard Mayer, M.D.		
/s/ Anand Shah, M.D.	Director	March 31, 2022
Anand Shah, M.D.		
/s/ Tom Heyman	Director	March 31, 2022
Tom Heyman		
/s/ Michael Wyzga	Director	March 31, 2022
Michael Wyzga		
/s/ Redonda Miller, M.D., M.B.A.	Director	March 31, 2022
Redonda Miller, M.D., M.B.A.		
/s/ Ellen R. Marram, M.B.A.	Director	March 31, 2022
Ellen Marram, M.B.A.		

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Adagio Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2021 and December 31, 2020, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows for the year ended December 31, 2021 and for the period from June 3, 2020 (inception) to December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and December 31, 2020, and the results of its operations and its cash flows for the year ended December 31, 2021 and for the period from June 3, 2020 to December 31, 2020 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts
March 31, 2022

We have served as the Company's auditor since 2021.

ADAGIO THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31,	
	2021	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 542,224	$ 114,988
Marketable securities	49,194	—
Prepaid expenses and other current assets	25,293	2,394
Total current assets	616,711	117,382
Property and equipment, net	83	—
Other non-current assets	3,297	—
Total assets	$ 620,091	$ 117,382
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 5,783	$ 8,153
Accrued expenses	56,277	4,919
Total current liabilities	62,060	13,072
Early-exercise liability	6	11
Other non-current liabilities	6	—
Total liabilities	62,072	13,083
Commitments and contingencies (Note 8)		
Convertible preferred stock (Series A, B and C), $0.0001 par value; no shares authorized, issued and outstanding at December 31, 2021; 12,647,934 shares authorized, issued and outstanding at December 31, 2020; aggregate liquidation preference of $0 and $169,900 at December 31, 2021 and December 31, 2020, respectively	—	169,548
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at December 31 2021; no shares authorized, issued and outstanding at December 31, 2020	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 111,251,660 shares issued and 110,782,909 shares outstanding at December 31, 2021; 150,000,000 shares authorized, 28,193,240 shares issued and 5,593,240 shares outstanding as of December 31, 2020	11	1
Treasury stock, at cost; 468,751 shares and 22,600,000 shares at December 31, 2021 and December 31, 2020, respectively	—	(85)
Additional paid-in capital	850,125	154
Accumulated other comprehensive loss	(8)	—
Accumulated deficit	(292,109)	(65,319)
Total stockholders' equity (deficit)	558,019	(65,249)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 620,091	$ 117,382

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

ADAGIO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
Operating expenses:		
Research and development[(1)]	$ 182,891	$ 21,992
Acquired in-process research and development[(2)]	7,500	40,125
Selling, general and administrative	36,517	3,210
Total operating expenses	226,908	65,327
Loss from operations	(226,908)	(65,327)
Other income (expense):		
Other income (expense), net	118	8
Total other income (expense), net	118	8
Net loss	(226,790)	(65,319)
Other comprehensive income (loss):		
Unrealized loss on available-for-sale securities, net of tax	(8)	—
Comprehensive loss	$ (226,798)	$ (65,319)
Net loss per share attributable to common stockholders, basic and diluted	$ (5.32)	$ (18.10)
Weighted-average common shares outstanding, basic and diluted	42,621,265	3,608,491

(1) Includes related-party amounts of $4,150 for the year ended December 31, 2021 and $595 for the period from June 3, 2020 (inception) to December 31, 2020 (see Note 7).

(2) Includes related-party amounts of $7,500 for the year ended December 31, 2021 and $39,915 for the period from June 3, 2020 (inception) to December 31, 2020 (see Note 7).

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

ADAGIO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
Balances at June 3, 2020 (Inception)	—	$ —	—	$ —	—	$ —	$ —	$ —	$ —	$ —
Issuance of common stock at inception	—	—	21,250,000	2	—	—	(2)	—	—	—
Issuance of Series A convertible preferred stock in exchange for assigned rights, license and repurchased common stock	5,000,000	40,000	(21,250,000)	(2)	21,250,000	(85)	2	—	—	(85)
Issuance of Series A convertible preferred stock, net of issuance costs of $194	6,237,500	49,706	—	—	—	—	—	—	—	—
Issuance of Series B convertible preferred stock, net of issuance costs of $158	1,410,434	79,842	—	—	—	—	—	—	—	—
Issuance of restricted common stock upon early exercise of stock options	—	—	6,943,240	1	—	—	(1)	—	—	—
Repurchase of unvested restricted common stock	—	—	(1,350,000)	—	1,350,000	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	155	—	—	155
Net loss	—	—	—	—	—	—	—	—	(65,319)	(65,319)
Balances at December 31, 2020	12,647,934	$ 169,548	5,593,240	$ 1	22,600,000	$ (85)	$ 154	$ —	$ (65,319)	$ (65,249)

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

ADAGIO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
Balances at December 31, 2020	12,647,934	$ 169,548	5,593,240	$ 1	22,600,000	$ (85)	$ 154	$ —	$ (65,319)	$ (65,249)
Issuance of Series C convertible preferred stock, net of issuance costs of $337	4,296,550	335,163	—	—	—	—	—	—	—	—
Issuance of common stock	—	—	6,000	—	—	—	66	—	—	66
Issuance of common stock upon completion of initial public offering, net of commissions, underwriting discounts and offering costs	—	—	20,930,000	2	—	—	327,518	—	—	327,520
Conversion of convertible preferred stock to common stock	(16,944,484)	(504,711)	84,722,420	8	—	—	504,703	—	—	504,711
Retirement of treasury stock	—	—	—	—	(22,600,000)	$ 85	(85)	—	—	—
Vesting of restricted common stock from early-exercised options	—	—	—	—	—	—	5	—	—	5
Repurchase of unvested restricted common stock	—	—	(468,751)	—	468,751	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	17,764	—	—	17,764
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	—	—	—	—	(226,790)	(226,790)
Balances at December 31, 2021	—	$ —	110,782,909	$ 11	468,751	$ —	$ 850,125	$ (8)	$ (292,109)	$ 558,019

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

ADAGIO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
Cash flows from operating activities:		
Net loss	$ (226,790)	$ (65,319)
Adjustments to reconcile net loss to net cash used in operating activities:		
Non-cash acquired in-process research and development	—	39,915
Stock-based compensation expense	17,764	155
Net amortization of premiums and accretion of discounts on marketable securities	1,430	—
Non-cash payments	66	—
Depreciation expense	1	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(22,899)	(2,394)
Accounts payable	(2,370)	8,153
Accrued expenses	51,358	4,919
Other non-current assets	(3,297)	—
Other non-current liabilities	1	—
Net cash used in operating activities	(184,736)	(14,571)
Cash flows from investing activities:		
Purchases of marketable securities	(188,627)	—
Maturities of marketable securities	138,000	—
Purchases of property and equipment	(84)	—
Net cash used in investing activities	(50,711)	—
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	335,163	129,548
Proceeds from issuance of common stock, net of commissions and underwriting discounts	330,905	—
Payments of initial public offering costs	(3,385)	—
Proceeds from early exercises of stock options	—	14
Payments for repurchases of restricted common stock	—	(3)
Net cash provided by financing activities	662,683	129,559
Net increase in cash and cash equivalents	427,236	114,988
Cash and cash equivalents at beginning of period	114,988	—
Cash and cash equivalents at end of period	$ 542,224	$ 114,988
Supplemental disclosure of non-cash financing activities:		
Issuance of Series A convertible preferred stock in exchange for assigned rights, license and repurchased common stock	$ —	$ 40,000

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

1. Nature of the Business and Basis of Presentation

Adagio Therapeutics, Inc., together with its consolidated subsidiary (the "Company"), is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of differentiated products for the prevention and treatment of infectious diseases. The company is developing its lead product candidate, adintrevimab, for the prevention and treatment of COVID-19, the disease caused by the virus SARS-CoV-2 and its variants. Beyond COVID-19, Adagio is leveraging robust antibody discovery and development capabilities that have enabled expedited advancement of adintrevimab into clinical trials to develop therapeutic or preventative options for other infectious diseases, such as additional coronaviruses and influenza. The Company initiated clinical trials for adintrevimab in February 2021. Adintrevimab is designed to be a potent, long-acting and broadly neutralizing antibody for both the prevention and treatment of COVID-19. The Company was incorporated in the State of Delaware in June 2020. The Company operates as a virtual company and plans to maintain a corporate headquarters for general and administrative purposes only. In addition, the Company engages third parties, including Adimab, LLC ("Adimab") and The Scripps Research Institute ("TSRI"), to perform ongoing research and development and other services on its behalf.

The Company is subject to a number of risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, completing clinical trials, the ability to raise additional capital to fund operations, obtaining regulatory approval for product candidates, market acceptance of products, competition from substitute products, protection of proprietary intellectual property, compliance with government regulations, the impact of COVID-19, dependence on key personnel, the ability to attract and retain qualified employees, and reliance on third-party organizations for the manufacturing, clinical and commercial success of its product candidates.

In July 2021, the Company effected a five-for-one stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 9). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the preferred stock conversion ratios.

In August 2021, the Company completed its initial public offering ("IPO") pursuant to which it issued and sold 20,930,000 shares of its common stock, including 2,730,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were approximately $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all shares of the Company's convertible preferred stock then outstanding converted into 84,722,420 shares of common stock (see Note 10).

The Company has not generated any revenue since inception. The Company's lead product candidate will require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales, including government supply contracts.

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. The Company has primarily funded its operations with proceeds from sales of convertible preferred stock and proceeds from the Company's initial public offering of common stock. The Company has incurred losses and negative cash flows from operations since its inception, including a net loss of $226.8 million for the year ended December 31, 2021. As of December 31, 2021, the Company had an accumulated deficit of $292.1 million. The Company expects to continue to generate operating losses for the foreseeable future. As of March 31, 2022, the issuance date of the consolidated financial statements for the year ended December 31, 2021, the Company expects that its cash, cash equivalents and marketable securities, would be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of the annual consolidated financial statements.

The Company expects to seek additional funding through equity offerings, government or private-party grants, debt financings or other capital sources, including collaborations with other companies or other strategic transactions. The Company

may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or rights of the Company's stockholders.

If the Company is unable to obtain sufficient capital, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Impact of the COVID-19 Coronavirus

In March 2020, the World Health Organization declared the outbreak of COVID-19 a global pandemic. The evolving and constantly changing impact of the pandemic will directly affect the potential commercial prospects of adintrevimab for the prevention and treatment of COVID-19. The severity of the COVID-19 pandemic and the continued emergence of variants of concern (such as the widespread Omicron and Delta variants), the availability, administration and acceptance of vaccines, monoclonal antibodies, antiviral agents and other therapeutic modalities, the introduction of local, national and/or employer vaccine mandates, and the potential development of "herd immunity" by the global population will affect the design and enrollment of the Company's clinical trials, the potential regulatory authorization or approval of the Company's product candidates and the commercialization of the Company's product candidates, if approved.

In addition, the Company's business and operations may be more broadly adversely affected by the COVID-19 pandemic. The COVID-19 outbreak and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services has fallen. The global COVID-19 pandemic continues to evolve rapidly, and the Company will continue to monitor it closely. The ultimate extent of the impact of the COVID-19 pandemic on the Company's business, financial condition, operations and product development timelines and plans remains highly uncertain and will depend on future developments, including the duration and spread of outbreaks and the continued emergence of variants, its impact on the Company's clinical trial design and enrollment, trial sites, contract research organizations, or CROs, contract development and manufacturing organizations, or CDMOs, and other third parties with which the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. To date, the Company has experienced some delays and disruptions in its development activities as a result of the COVID-19 pandemic. Some of the Company's CROs, CDMOs and other service providers also continue to be impacted. The Company will continue to monitor developments as we address the disruptions, delays and uncertainties relating to the COVID-19 pandemic. These developments and the impact of the COVID-19 pandemic on the financial markets and the overall economy are highly uncertain and cannot be predicted. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results and operations may be materially adversely affected and may affect the Company's ability to raise capital.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of Adagio Therapeutics, Inc. and its wholly owned subsidiary, Adagio Therapeutics Security Corporation. All intercompany balances and transactions have been eliminated in consolidation.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, research and development expenses and related prepaid or accrued costs. Prior to the IPO, significant estimates and assumptions also included the valuation of common stock and resulting stock-based compensation expense. The Company

bases its estimates on historical experience, known trends and other market-specific or relevant factors it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ materially from those estimates or assumptions.

The Company is monitoring the potential impact of the COVID-19 pandemic on its business and consolidated financial statements. The Company is not aware of any specific event or circumstance that would require any update to its estimates or judgments reflected in these consolidated financial statements or a revision of the carrying value of its assets or liabilities as of the issuance date of these consolidated financial statements. These estimates may change as new events occur and additional information is obtained.

Deferred Offering Costs

The Company capitalizes certain legal, 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 recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of preferred stock or in stockholders' equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the consolidated statement of operations and comprehensive loss. In conjunction with the IPO in August 2021, the Company recorded deferred offering costs, which were initially capitalized and subsequently recorded as stockholders' equity (deficit) as a reduction of additional paid-in capital. The Company had no deferred offering costs recorded as of December 31, 2021 and 2020.

Concentrations of Credit Risk, Significant Suppliers and License Rights

Financial instruments that potentially expose the Company to concentrations of credit risk consist of cash, cash equivalents and marketable securities. The Company invests its excess cash in money market funds and marketable securities that are subject to minimal credit and market risks. The Company maintains its cash, cash equivalents and marketable securities at two accredited financial institutions that it believes are creditworthy. From time to time, these deposits may exceed federally insured limits. The Company has not experienced any losses historically in these accounts. Accordingly, the Company does not believe it is exposed to unusual credit risk related to its cash, cash equivalents and marketable securities beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party organizations to manufacture and process its product candidates for its development programs. In particular, the Company relies on a single third-party contract manufacturer to produce and process its current product candidate, adintrevimab, and to manufacture supply of its current product candidate for preclinical and clinical activities (see Note 8). The Company also currently relies on this same third-party contract manufacturer for any anticipated requirements of commercial supply, including both drug substance and drug product. The Company expects to continue to be dependent on a small number of manufacturers to supply it with its requirements for all products. The Company's research and development programs, including any associated potential commercialization efforts, could be adversely affected by a significant interruption in the supply of the necessary materials.

The Company is dependent on a limited number of third parties that provide license rights used by the Company in the development and potential commercialization of its product candidates and programs. Through December 31, 2021, the Company's research and development programs primarily relate to rights conveyed by Adimab and The Scripps Research Institute (see Note 7). The Company could experience delays in the development and potential commercialization of its product candidates and programs if the Adimab or The Scripps Research Institute agreements or any other license agreement utilized in the Company's research and development activities is terminated, if the Company fails to meet the obligations required under its arrangements, or if the Company is unable to successfully secure new strategic alliances or licensing agreements.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the acquisition date to be cash equivalents.

Marketable Securities

Marketable securities represent holdings of available-for-sale marketable debt securities in accordance with the Company's investment policy. The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company classified all of its marketable securities at December 31, 2021 as "available-for-sale" pursuant to ASC320, Investments – Debt and Equity Securities. Investments not classified as cash equivalents are presented as either short-term or long-term investments based on both their maturities as well as the time period the Company intends to hold such securities. Available-for-sale securities are maintained by an investment manager and consist of U.S. Treasury securities. Available-for-sale securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity (deficit) until realized. Any premium or discount arising at purchase is amortized or accreted to interest expense or income over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other income (expense). There were no material realized gains or losses on marketable securities recognized for the year ended December 31, 2021.

The Company reviews marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations and comprehensive loss if the Company has experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that the Company will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and duration of the impairment and changes in value subsequent to the end of the period. There were no other-than-temporary impairments of investments recognized for the year ended December 31, 2021.

Fair Value Measurements

Certain assets of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 4). The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Machinery and equipment	3 to 5 years
Furniture and fixtures	3 to 5 years
Leasehold improvements	Shorter of lease term of useful life

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in

loss from operations. Expenditures for repairs and maintenance that do not improve or extend the life of the respective assets are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. The Company continually evaluates long-lived assets for potential impairment whenever events or changes in circumstances indicate that the carrying value of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares the carrying values of the asset group to the expected future undiscounted cash flows that the asset group is expected to generate from the use and eventual disposition of the long-lived asset group. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. If such asset group is considered to be impaired, the impairment loss to be recognized would be based on the excess of the carrying value of the impaired asset group over its fair value. The Company did not recognize any impairment losses on long-lived assets during the years ended December 31, 2021 and 2020.

Leases

The Company accounts for leases under ASC840, *Leases*. The Company records monthly rent expense on a straight-line basis, equal to the total of the payments due over the lease term, divided by the number of months of the lease term. The difference between rent expense recorded and the amount paid was charged to deferred rent.

Patent Costs

Costs to secure, defend and maintain patents, including those incurred in connection with filing and prosecuting patent applications, are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred for patent-related expenditures are classified as general and administrative expenses.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential. The Company's chief operating decision maker reviews the Company's financial information on an aggregated basis for purposes of assessing performance and allocating resources.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including expenses incurred under agreements with external vendors and consultants engaged to perform non-clinical studies, preclinical studies and clinical trials as well as to manufacture research and development materials for use in such studies and trials; salaries and related personnel costs; stock-based compensation; consultant fees; and third-party license fees.

Nonrefundable advance payments for goods and services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Accrued Research and Development Costs

The Company has entered into various research, development and manufacturing contracts with third-party service providers, including contract research organizations and contract manufacturing organizations. With the exception of the Company's manufacturing arrangement with WuXi Biologics (Hong Kong) Limited (see Note 8), these agreements are generally cancelable. The Company recognizes research and development expense associated with such arrangements as the costs are incurred and records accruals for estimated ongoing research, development and manufacturing costs, where necessary. When billing terms under these contracts do not coincide with the timing of when the work is performed, the Company is required to make estimates of outstanding obligations to those third parties as of period end. Any accrual estimates are based on a number of factors, including the Company's knowledge of the progress towards completion of the specific tasks to be performed, invoicing to date under the contracts, communication from the vendors of any actual costs incurred during the

period that have not yet been invoiced and the costs included in the contracts. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the estimates made by the Company. The historical accrual estimates made by the Company have not been materially different from the actual costs.

Asset Acquisitions and Acquired In-Process Research and Development Expenses

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the cost to acquire the asset or group of assets, which includes transaction costs. Goodwill is not recognized in asset acquisitions. In an asset acquisition, the cost allocated to acquire in-process research and development ("IPR&D") with no alternative future use is recognized as expense on the acquisition date.

Contingent consideration in asset acquisitions payable in the form of cash is recognized in the period the triggering event is determined to be probable of occurrence and the related amount is reasonably estimable. Such amounts are expensed or capitalized based on the nature of the associated asset at the date the related contingency is resolved.

Acquired IPR&D expense recognized for the year ended December 31, 2021 consisted of payments due for milestones achieved under the Adimab arrangement (see Note 7). Acquired IPR&D expense recognized for the period from June 3, 2020 (inception) to December 31, 2020 consisted of the upfront consideration paid in connection with the Company's acquisition of assigned rights and an intellectual property license from Adimab and other in-licensing arrangements executed during the period (see Note 7).

Stock-Based Compensation

The Company grants stock-based awards to employees, directors and non-employee consultants in the form of stock options to purchase shares of its common stock. The Company measures stock options with service-based vesting granted to employees, non-employees and directors based on the fair value on the date of grant using the Black-Scholes option-pricing model. The Company has issued awards with only service-based vesting conditions through December 31, 2021 and 2020.

Compensation expense for awards granted to employees and directors for their service on the board of directors is recognized on a straight-line basis over the requisite service period of the respective award, which is generally the vesting period of the award. Compensation expense for awards granted to non-employees is recognized in the same period and manner as if the Company had paid cash for the goods or services provided, which is generally the vesting period of the award. The Company accounts for forfeitures of stock-based awards as they occur.

The Company classifies stock-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income, and to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any

resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties. The Company had no amounts accrued for interest and penalties on its consolidated balance sheets as of December 31, 2021 and 2020.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the year ended December 31, 2021, the Company's only element of other comprehensive income (loss) was unrealized gains (losses) on marketable securities. There was no difference between net loss and comprehensive loss for the period from June 3, 2020 (inception) to December 31, 2020.

Net Loss per Share

The Company follows the two-class method when computing net income (loss) per share attributable to common stockholders as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income (loss) for the period to be allocated between common and participating securities based upon their respective rights to share in the undistributed earnings as if all income (loss) for the period had been distributed. The Company considers its convertible preferred stock to be participating securities as, in the event a dividend is paid on common stock, the holders of convertible preferred stock would be entitled to receive dividends on a basis consistent with the common stockholders. The Company also considers the shares issued upon the early exercise of stock options that are subject to repurchase to be participating securities because holders of such shares have non-forfeitable dividend rights in the event a dividend is paid on common stock. There is no allocation required under the two-class method during periods of loss since the participating securities do not have a contractual obligation to share in the losses of the Company.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period, excluding shares of unvested restricted common stock. Diluted net income (loss) per share attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For the purposes of this calculation, the Company's outstanding stock options, convertible preferred stock and unvested restricted common stock are considered potential dilutive common shares.

The Company has generated a net loss for each of the periods presented. Accordingly, basic and diluted net loss per share attributable to common stockholders are the same because the inclusion of the potentially dilutive securities would be anti-dilutive.

Emerging Growth Company

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and nonpublic companies, the Company will adopt the new or revised standard at the time nonpublic companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for nonpublic companies.

Recently Adopted Accounting Pronouncements

In August 2018, the FASB issued ASU No. 2018-15, Intangibles–Goodwill and Other—Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract ("ASU 2018-15"). The amendments in ASU 2018-15 align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license).

Accordingly, the update requires entities in a hosting arrangement that is a service contract to follow the guidance in ASC 350-40, Internal-Use Software ("ASC 350-40") to determine which implementation costs to capitalize as an asset related to the service contract and which costs to expense. Costs to develop or obtain internal-use software that cannot be capitalized under ASC 350-40, such as training costs and certain data conversion costs, also cannot be capitalized for a hosting arrangement that is a service contract. Therefore, an entity in a hosting arrangement that is a service contract determines which project stage an implementation activity relates to. Costs for implementation activities in the application development stage are capitalized depending on the nature of the costs, while costs incurred during the preliminary project and post-implementation stages are expensed as the activities are performed. ASU 2018-15 also requires entities to expense the capitalized implementation costs of a hosting arrangement that is a service contract over the term of the hosting arrangement. ASU 2018-15 was effective for public entities for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. For nonpublic entities, ASU 2018-15 is effective for annual reporting periods beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2021. Early adoption is permitted, including adoption in any interim period. ASU 2018-15 is applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company adopted ASU 2018-15 as of January 1, 2021 on a prospective basis and the adoption did not have a material impact on its consolidated financial statements and related disclosures.

In December 2019, the FASB issued ASU No. 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* ("ASU 2019-12"). ASU 2019-12 eliminates certain exceptions related to the approach for intraperiod tax allocation, the methodology for calculating income taxes in an interim period and the recognition of deferred tax liabilities for outside basis differences. The update also clarifies and simplifies other aspects of the accounting for income taxes. For public entities, ASU 2019-12 is required to be adopted for annual periods beginning after December 15, 2020, including interim periods within those fiscal years. For nonpublic entities, ASU 2019-12 is effective for annual periods beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. Early adoption is permitted, including adoption in any interim period for which financial statements have not yet been issued or made available for issuance. An entity that elects to early adopt the update in an interim period should reflect any adjustments as of the beginning of the annual period that includes that interim period. Additionally, an entity that elects early adoption must adopt all the amendments in the update in the same period. The Company adopted ASU 2019-12 as of January 1, 2021 and the adoption did not have a material impact on its consolidated financial statements and related disclosures.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02" or "ASC 842"), as subsequently amended. ASC 842 sets forth the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). ASC 842 replaces the existing guidance in ASC No. 840, *Leases* ("ASC 840"). ASC 842 requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification determines whether lease expense is recognized based on an effective interest method for finance leases or on a straight-line basis over the term of the lease for operating leases. In addition, a lessee is also required to record (i) a right-of-use asset and a lease liability on its balance sheets for all leases with a term of greater than 12 months regardless of their classification and (ii) lease expense on its statement of operations for operating leases and amortization and interest expense on its statement of operations for financing leases. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases under ASC 840. ASC 842 also requires lessees and lessors to disclose key information about their leasing transactions. In July 2018, the FASB issued ASU No. 2018-11, *Leases (Topic 842)*, which added an optional transition method that allows companies to adopt the standard as of the beginning of the year of adoption as opposed to the earliest comparative period presented. In November 2019, the FASB issued guidance delaying the effective date for all entities, except for public entities. For public entities, ASU 2016-02 was effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. In June 2020, the FASB issued ASU No. 2020-05, *Revenue from Contracts with Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities* ("ASU 2020-05"), which delayed the adoption date of ASU 2016-02 for nonpublic entities. For nonpublic entities, ASU 2016-02 is effective for annual periods beginning after December 15, 2021, including interim periods within annual periods beginning after December 15, 2022. Early adoption is permitted, including in an interim period. Entities are required to adopt ASC 842 using a modified retrospective transition method. The Company will recognize its lease on the balance sheet on the adoption date of January 1, 2022, by recording a right-of-use asset and a corresponding lease liability. The Company does not expect the adoption of ASC 842 to have a material impact on the Company's consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"), and also issued subsequent amendments to the initial guidance: ASU 2018-19, ASU 2019-04 and ASU 2019-05 (collectively, "Topic 326"). The main objective of this update is to provide

financial statement users with more decision-useful information about the expected credit losses on financial instruments and other commitments to extend credit held by a reporting entity at each reporting date. To achieve this objective, the amendments in this update replace the incurred loss impairment methodology in current guidance with a methodology that reflects expected credit losses and requires consideration of a broader range of reasonable and supportable information to inform credit loss estimates. Under ASU 2016-13, expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities are required to be recorded through an allowance for credit losses. The update also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which the carrying value exceeds fair value. The measurement of expected credit losses will be based on relevant information about past events, including historical experience, current conditions and reasonable and supportable forecasts that affect the collectability of the reported amount. ASU 2016-13 also establishes additional disclosure requirements related to credit risks. For public entities that qualify as a filer with the Securities and Exchange Commission, excluding entities eligible to be smaller reporting companies, ASU 2016-13 is effective for annual periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. In November 2019, the FASB issued ASU No. 2019-10, which deferred the effective date for nonpublic entities to annual reporting periods beginning after December 15, 2022, including interim periods within those fiscal years. ASU 2016-13 is applied by means of a cumulative-effect adjustment to the opening retained earnings as of the beginning of the first reporting period in which the guidance is effective. The Company is currently evaluating the potential impact that the adoption of this standard may have on its consolidated financial statements and related disclosures.

In August 2020, the FASB issued ASU No. 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity* ("ASU 2020-06"). ASU 2020-06 was issued to reduce the complexity associated with accounting for certain financial instruments with characteristics of liabilities and equity. ASU 2020-06 reduces the number of accounting models for convertible debt instruments and convertible preferred stock and improves the disclosures for convertible instruments and related earnings per share guidance. ASU 2020-06 also amends the guidance for the derivatives scope exception for contracts in an entity's own equity and improves and amends the related earnings per share guidance. For public entities that qualify as a filer with the Securities and Exchange Commission, excluding entities eligible to be smaller reporting companies, ASU 2020-06 is effective for fiscal annual periods beginning after December 15, 2021, including interim periods within those fiscal years. For nonpublic entities, ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020, including interim periods within those fiscal years. ASU 2020-06 must be adopted as of the beginning of its annual fiscal year. ASU 2020-06 may be adopted through either a modified retrospective method of transition or a fully retrospective method of transition. The Company is currently evaluating the potential impact that the adoption of this standard may have on its consolidated financial statements and related disclosures.

3. Marketable Securities

Treasury securities held by the Company are classified as available-for-sale pursuant to ASC 320, Investments – Debt and Equity Securities, and carried at fair value in the accompanying consolidated balance sheet on a settlement date basis. The following tables summarize the gross unrealized gains and losses of the Company's marketable securities as of December 31, 2021 (in thousands):

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury securities	$ 49,202	$ —	$ (8)	$ 49,194

No available-for-sale securities held as of December 31, 2021 had remaining maturities greater than twelve months.

The Company did not hold any available-for-sale securities as of December 31, 2020.

4. Fair Value Measurements

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 541,220	$ —	$ —	$ 541,220
Marketable securities:				
U.S. Treasury securities	49,194	—	—	49,194
	$ 590,414	$ —	$ —	$ 590,414

	Fair Value Measurements at December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market fund	$ 39,006	$ —	$ —	$ 39,006
	$ 39,006	$ —	$ —	$ 39,006

The money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy.

The U.S Treasury securities were valued by the Company based on Level 1 inputs. In determining the fair value of the U.S. Treasury securities, the Company relied on quoted prices for identical securities in active markets.

There were no changes to the valuation methods for the year ended December 31, 2021 or the period from June 3, 2020 (inception) to December 31, 2020.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Level 1, Level 2 or Level 3 during the year ended December 31, 2021 or the period from June 3, 2020 (inception) to December 31, 2020.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2021	2020
Prepaid external research, development and manufacturing costs	$ 20,582	$ 2,253
Prepaid insurance	3,190	41
Prepaid compensation and other	1,521	100
	$ 25,293	$ 2,394

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2021	2020
Accrued external research, development and manufacturing costs	$ 48,590	$ 3,853
Accrued professional and consultant fees	2,155	237
Accrued employee compensation	4,945	794
Other	587	35
	$ 56,277	$ 4,919

7. License and Collaboration Agreements

Adimab Assignment Agreement

In July 2020, the Company entered into an Assignment and License Agreement with Adimab ("Adimab Assignment Agreement"). Under the terms of the agreement, Adimab assigned to the Company all rights, title and interest in and to certain of its coronavirus-specific antibodies ("CoV Antibodies"), including modified or derivative forms thereof, and related intellectual property ("Adimab CoV Assets"). In addition, Adimab granted to the Company a non-exclusive, worldwide, royalty-bearing, sublicensable license to certain of its platform patents and technology for the development, manufacture and commercialization of the CoV Antibodies and pharmaceutical products containing or comprising one or more CoV Antibodies (each, a "Product") for all indications and uses, with the exception of certain diagnostic uses and use as a research reagent (the "Field"). The Company is entitled to sublicense the assigned rights and licensed intellectual property solely with respect to any CoV Antibody or Product, subject to specified conditions of the agreement. The Company is obligated to use commercially reasonable efforts to achieve specified development and regulatory milestones for Products in certain major markets and to commercialize a product in any country in which the Company obtains marketing approval.

Pursuant to the terms of the Adimab Assignment Agreement, the parties will establish one or more work plans that set forth the activities to be performed under the agreement (each, a "Work Plan"), and each party is responsible for performing the obligations to which it is assigned under such Work Plans. Upon execution of the Adimab Assignment Agreement, the Company and Adimab agreed on an initial work plan that outlined the services that will be performed commencing at inception of the arrangement. The Company is obligated to pay Adimab quarterly for its services performed under each Work Plan at a specified full-time equivalent rate. Otherwise, the Company is solely responsible for the development, manufacture and commercialization of the CoV Antibodies and associated Products at its own cost and expense. The Company is solely responsible for preparing and submitting all investigational new drug applications, new drug applications, biologics license applications and other regulatory filings for the CoV Antibodies and Products in the Field, and for obtaining and maintaining all marketing approvals for Products in the Field, at its sole expense. Additionally, the Company has the sole right to prosecute, maintain, enforce and defend patents covering the CoV Antibodies and Products, all at its own expense.

In July 2020, in consideration for the rights assigned and license conveyed under the Adimab Assignment Agreement, the Company issued 5,000,000 shares of its Series A convertible preferred stock (the "Series A Preferred Stock"), then having a fair value of $40.0 million, to Adimab. Concurrently, Adimab relinquished 21,250,000 shares of the Company's common stock to the Company, then having a fair value of $85,000. Additionally, the Company is obligated to pay Adimab up to $16.5 million upon the achievement of specified development and regulatory milestones for the first Product under the agreement that achieves such specified milestones and up to $8.1 million upon the achievement of specified development and regulatory milestones for the second Product under the agreement that achieves such specified milestones. The maximum aggregate amount of milestone payments payable under the agreement for any and all Products is $24.6 million; however, milestone payments do not accrue for certain *in vitro* diagnostic devices consisting of or containing CoV Antibodies.

In February 2021, the Company achieved the first specified milestone under the agreement upon dosing of the first patient in a Phase 1 global clinical trial evaluating adintrevimab, which obligated the Company to make a $1.0 million milestone payment to Adimab. In April 2021, the Company achieved the second specified milestone under the agreement upon dosing of the first patient in a Phase 2 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated the Company to make a $2.5 million milestone payment to Adimab. In August 2021, the Company achieved the third specified milestone under the agreement upon dosing of the first patient in a Phase 3 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated the Company to make a $4.0 million milestone payment to Adimab. The Company recognized each expense when achievement of each of the first, second and third milestones became probable of achievement in February, April and August 2021, respectively. The next potential milestone under the Adimab Assignment Agreement is a $4.0 million milestone related to the acceptance of the filing of the first New Drug Application ("NDA") for a Product by the FDA, which was not considered probable as of December 31, 2021.

During the year ended December 31, 2021, the Company recognized $7.5 million as in-process research and development ("IPR&D") expense in connection with contingent consideration payable under the Adimab Assignment Agreement. For the period from June 3, 2020 (inception) to December 31, 2020, the Company recognized $39.9 million as IPR&D expense in connection with the upfront consideration payable under the Adimab Assignment Agreement to acquire rights to Adimab's antibodies relating to COVID-19 and SARS and related intellectual property and a license to certain of Adimab's platform patents and technology for use in the research and development of the Company's product candidates.

The Company is obligated to pay Adimab royalties of a mid single-digit percentage based on net sales of any Products, once commercialized. The royalty rate is subject to reductions specified under the agreement. Royalties are due on a Product-by-Product and country-by-country basis beginning upon the first commercial sale of each Product and ending on the later of (i) 12 years after the first commercial sale of such Product in such country and (ii) expiration of the last valid claim of a patent covering such Product in such country ("Royalty Term"). In addition, the Company is obligated to pay Adimab royalties of a specified percentage in the range of 45% to 55% of any compulsory sublicense consideration received by the Company in lieu of certain royalty payments. Except for the first milestone payment of $1.0 million, the second milestone payment of $2.5 million and the third milestone payment of $4.0 million, which were paid by the Company to Adimab in March, May and September 2021, respectively, no other milestone, royalty or other contingent payments had become due to Adimab through December 31, 2021.

Unless earlier terminated, the Adimab Assignment Agreement remains in effect until the expiration of the last-to-expire Royalty Term for any and all Products. The Company may terminate the agreement at any time for any or no reason upon advance written notice to Adimab. Either party may terminate the agreement in the event of a material breach by the other party that is not cured within specified periods, except that after the initiation of the first clinical trial of a Product, Adimab may only terminate the agreement for an uncured material breach by the Company for its due diligence obligation or a payment obligation. Upon any termination of the agreement prior to its expiration, all licenses and rights granted pursuant to the arrangement will automatically terminate and revert to the granting party and all other rights and obligations of the parties will terminate.

The Company concluded that the Adimab Assignment Agreement represented an asset acquisition of IPR&D assets with no alternative future use. The arrangement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset. Therefore, the aggregate acquisition cost of $39.9 million was recognized as acquired IPR&D expense in July 2020. The $39.9 million of costs to acquire the IPR&D assets was determined as a result of the Company's allocation of the $40.0 million aggregate fair value of the 5,000,000 shares of the Series A Preferred Stock that the Company issued to Adimab on the acquisition date in exchange for (i) the IPR&D assets acquired from Adimab and (ii) 21,250,000 shares of the Company's common stock that it repurchased from Adimab on that same date. The Company allocated the $40.0 million fair value of the 5,000,000 shares of Series A Preferred Stock to the IPR&D assets and to the repurchased common stock based on their relative fair values on the acquisition date. As of that date and before allocation, the Company determined that the fair value of the repurchased common stock was $85,000, based on the results of a third-party valuation, and that the fair value of the IPR&D assets was $40.0 million. The Company determined the fair value of the 5,000,000 shares of Series A Preferred Stock based on the $8.00 price per share paid for the stock by new investors in the Company's Series A Preferred Stock financing, which closed on the same date as the date on which the Company acquired the CoV Antibodies and Adimab CoV Assets under the Adimab Assignment Agreement.

For the year ended December 31, 2021 and the period from June 3, 2020 (inception) to December 31, 2020, the Company recognized $7.5 million and $39.9 million, respectively, as IPR&D expense in connection with upfront consideration and contingent consideration payable under the Adimab Assignment Agreement.

Amounts paid with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement are recognized as research and development expense as such amounts are incurred. For the year ended December 31, 2021 and for the period from June 3, 2020 (inception) to December 31, 2020, the Company recognized $1.3 million and $0.6 million, respectively, of expense in connection with services provided by Adimab. Please refer to Note 15 for additional information.

Adimab Collaboration Agreement

On May 21, 2021, the Company entered into a Collaboration Agreement with Adimab (the "Adimab Collaboration Agreement") for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the agreement, the Company and Adimab will collaborate on research programs for a specified number of targets selected by the Company within a specified time period. Under the Adimab Collaboration Agreement, Adimab granted the Company a worldwide, non-exclusive license to certain of its platform patents and technology and antibody patents to perform the Company's responsibilities during the ongoing research period and for a specified evaluation period thereafter (the "Evaluation Term"). In addition, the Company granted Adimab a license to certain of the Company's patents and intellectual property solely to perform Adimab's responsibilities under the research plans. Under the agreement, the Company has an exclusive option, on a program-by-program basis, to obtain licenses and assignments to commercialize selected products containing or comprising antibodies directed against the applicable target, which option may be exercised upon the payment of a specified option fee for each program. Upon exercise of an option by the Company, Adimab will assign to the Company all right, title and interest in

the antibodies of the optioned research program and will grant the Company a worldwide, royalty-free, fully paid-up, non-exclusive, sublicensable license under the Adimab platform technology for the development, manufacture and commercialization of the antibodies for which the Company has exercised its options and products containing or comprising those antibodies. The Company is obligated to use commercially reasonable efforts to develop, seek marketing approval for, and commercialize one product that contains an antibody discovered in each research program.

The Company is obligated to pay Adimab a quarterly fee of $1.3 million, which may be cancelled at the Company's option at any time. For so long as the Company is paying such quarterly fee (or earlier if (i) the Company experiences a change of control after the third anniversary of the Adimab Collaboration Agreement or (ii) Adimab owns less than a specified percentage of the Company's equity), Adimab and its affiliates will not assist or direct certain third parties to discover or optimize antibodies that are intended to bind to coronaviruses or influenza viruses. The Company may also elect to decrease the scope of Adimab's exclusivity obligations and obtain a corresponding decrease in the quarterly fee. For the year ended December 31, 2021, the Company recognized $2.6 million of research and development expense related to the quarterly fee.

For each agreed upon research program that is commenced, the Company is obligated to pay Adimab quarterly for its services performed during a given research program at a specified full-time equivalent rate; a discovery delivery fee of $0.2 million; and an optimization completion fee of $0.2 million. For each option exercised by the Company to commercialize a specific research program, the Company is obligated to pay Adimab an exercise fee of $1.0 million. Amounts paid with respect to services performed by Adimab on the Company's behalf in each of the research programs under the Adimab Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. For the year ended December 31, 2021, the Company recognized $0.3 million of expense in connection with services provided by Adimab. Through December 31, 2021, the Company has not paid a drug delivery fee or optimization completion fee to Adimab and the Company has not exercised its option with respect to any program.

The Company is obligated to pay Adimab up to $18.0 million upon the achievement of specified development and regulatory milestones for each product under the agreement that achieves such milestones. The next potential milestone under the Adimab Collaboration Agreement is a $1.0 million milestone related to dosing of the first subject in a Phase I trial, which was not considered probable as of December 31, 2021. The Company is also obligated to pay Adimab royalties of a mid single-digit percentage based on net sales of any product under the agreement, subject to reductions for third-party licenses. The royalty term will expire for each product on a country-by-country basis upon the later of (i) 12 years after the first commercial sale of such product in such country and (ii) the expiration of the last valid claim of any patent claiming composition of matter or method of making or using any antibody identified or optimized under the Adimab Collaboration Agreement in such country.

In addition, the Company is obligated to pay Adimab for Adimab's performance of certain validation work with respect to certain antigens acquired from a third party. In consideration for this work, the Company is obligated to pay Adimab royalties of a low single-digit percentage based on net sales of products that contain such antigens for the same royalty term as antibody-based products, but the Company is not obligated to make any milestone payments for such antigen products. Through December 31, 2021, the Company has not paid any royalties to Adimab under the Adimab Collaboration Agreement.

The Adimab Collaboration Agreement will expire (i) if the Company does not exercise any option, upon the conclusion of the last Evaluation Term for the research programs, or (ii) if the Company exercises an option, on the expiration of the last royalty term for a product in a particular country, unless the agreement is earlier terminated. The Company may terminate the Adimab Collaboration Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either party may terminate the Adimab Collaboration Agreement in the event of a material breach by the other party that is not cured within specified periods. The Company concluded that the Adimab Collaboration Agreement represented an asset acquisition of IPR&D with no alternative future use. Therefore, payments made by the Company to Adimab for milestones achieved will be recognized as acquired IPR&D expense in the related period in which the services are performed or the related milestone is considered probable of achievement. Amounts paid with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. Please refer to Note 15 for additional information.

WuXi Cell Line License Agreement

In December 2020, the Company entered into a Cell Line License Agreement with WuXi Biologics (Hong Kong) Limited ("WuXi") (the "Cell Line License Agreement"), under which WuXi granted to the Company a non-exclusive, non-transferable, worldwide, royalty-bearing, sublicensable license to certain of its intellectual property, including certain patent rights associated with a proprietary cell line developed by WuXi for the exploitation of certain recombinant antibodies developed using such proprietary cell line (each, a "Licensed Product"). Each Licensed Product generated under the arrangement will be

produced from a transformed or transfected version of the proprietary cell line derived by WuXi (each of such transformed or transfected cell lines, a "Licensed Cell Line").

The Company was obligated to pay an upfront fee of $0.2 million to WuXi upon completion of cell bank generation for the first Licensed Cell Line created under the arrangement. Such amount became due in December 2020 and was an accrued expense as of December 31, 2020 and was paid as of December 31, 2021. The Company is also obligated to pay royalties in the range of 0.3% to 0.5% to WuXi based on net sales of any Licensed Products manufactured by the Company or a third party on its behalf. However, if the Company uses WuXi to manufacture all of its commercial supplies, no royalties would be owed by the Company to WuXi for net sales of Licensed Products. The Company has an option to buy out its royalty obligations on a Licensed Cell Line-by-Licensed Cell Line basis by making a one-time payment of $15.0 million to WuXi. Royalties are due on a Licensed Product-by-Licensed Product basis commencing on the date of the first commercial sale of the applicable product and continue for so long as the Company commercializes Licensed Products or until the Company exercises its option to buy out the royalty obligations. Through December 31, 2021, no royalties had become due to WuXi.

The Cell Line License Agreement remains in effect until it is terminated. The Company may terminate the Cell Line License Agreement at any time with notice to WuXi. WuXi may terminate the Cell Line License Agreement in the event the Company fails to make a payment when due under the arrangement and such non-payment is not cured within a specified period after notice. Either party may terminate the Cell Line License Agreement in the event of a material breach by the other party that is not cured within a specified period after notice. Upon termination of the Cell Line License Agreement, the license conveyed by WuXi to the Company will continue in full force and effect with respect to all Licensed Products manufactured using the Licensed Cell Line already generated under the arrangement, provided that the Company continues to pay its royalty obligations, if any.

The Company concluded that the Cell Line License Agreement represented an asset acquisition of IPR&D with no alternative future use. The arrangement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset. Therefore, the aggregate acquisition cost of $0.2 million, consisting solely of the upfront fee, was recognized as acquired IPR&D expense for the period from June 3, 2020 (inception) to December 31, 2020.

Research Collaboration and License Agreement with The Scripps Research Institute

In August 2021, the Company entered into a Research Collaboration and License Agreement (the "Research Agreement") with The Scripps Research Institute ("TSRI"). Under the terms of the Research Agreement, TSRI will perform research activities (the "Research Program") to identify vaccine candidates for the prevention, diagnosis or treatment of influenza or beta coronaviruses (the "Specified Field"). Unless otherwise mutually agreed by the parties, the Research Program will be completed by August 2023. Activities initiated under the Research Agreement for targets or indications pursued under the arrangement will be conducted in accordance with a research plan to be agreed upon by the parties (each, a "Research Plan"). Each of the parties is responsible for performing the tasks to which it is assigned under the Research Plans. The Company is obligated to provide the research funding necessary to carry out the Research Program pursuant to the budget outlined in each Research Plan. In August 2021, the Company paid TSRI $1.5 million in funding, which was credited against research funding payable by the Company under the Research Agreement. Additionally, the Company is obligated to make specified payments to TSRI to the extent that TSRI complies with certain exclusivity covenants.

Pursuant to the terms of the Research Agreement, the Company was granted an exclusive option (the "Option") to acquire an exclusive, worldwide, sublicensable license under TSRI's rights in certain patent rights and know-how for the exploitation of any vaccine product containing, comprised of, or derived from, any vaccine candidate identified or developed under the Research Program (each, a "TSRI Licensed Product") in the Specified Field. Any licenses granted under the arrangement are subject to certain exceptions, conditions and reserved rights. The Company's option is exercisable for a predefined period of time as outlined in the arrangement. Upon exercise of the Option, the Company is required to reimburse certain patent costs previously incurred by TSRI and bear all future related patent costs. Following the exercise of the Option, the Company has the sole right and responsibility for the further development and potential commercialization of the associated Licensed Product, at its sole cost and expense. As of December 31, 2021, the Company had not exercised its Option.

To the extent any TSRI Licensed Product covered by the Research Agreement is commercialized, the Company is obligated to pay TSRI royalties of a low single-digit percentage on a TSRI Licensed Product-by-Licensed Product and country-by-country basis based on a percentage of net sales, subject to reduction and floor. Royalties are payable for each product on a country-by-country basis through the later of (i) the expiration of the last valid claim of any patent covering such product in such country or (ii) 12 years from the first commercial sale of such product. The Research Agreement will expire when no

further royalties are due to TSRI. The Research Agreement may be early terminated upon mutual written consent of both parties. The Company may terminate the Research Agreement at any time upon advance written notice to TSRI or upon the appointment of certain personnel deemed unacceptable. In addition, TSRI may terminate the Research Agreement if the Company fails to perform or observe any contractual term in any material respect or in the event of a material breach by the Company that remains uncured for a specified period. Following early termination, all licenses will terminate and revert to TSRI, all sublicenses granted by the Company will automatically terminate, and any then-existing sublicensees will have the right to obtain a direct license from TSRI.

Amounts incurred for services performed by TSRI under each of the research plans are expensed to research and development expense as the services are rendered. For the year ended December 31, 2021, the Company recognized $2.3 million of expense associated with services performed under the Research Agreement.

8. Commitments and Contingencies

Operating Lease Commitments

In September 2021, the Company entered into a five year lease agreement (the "lease") for approximately 9,600 square feet of office space in Waltham, Massachusetts. The monthly rental payments under the lease, which include base rent charges of $0.4 million per year, are subject to periodic rent increases through September 2026.

The Company recognizes rent expense on a straight-line basis over the lease term and records deferred rent for rent expense incurred but not yet paid. The Company's rent expense for the year ended December 31, 2021 was $0.1 million.

License Agreements

The Company has entered into license agreements with Adimab, WuXi and TSRI (see Note 7).

Manufacturing Agreements

In December 2020, the Company entered into a Commercial Manufacturing Services Agreement with WuXi, which was amended and restated in August 2021 (as amended and restated, the "Commercial Manufacturing Agreement"). The Commercial Manufacturing Agreement outlines the terms and conditions under which WuXi will manufacture adintrevimab drug substance and drug product for commercial use.

The Company committed to minimum non-cancelable purchase obligations related to batches of adintrevimab drug substance and certain services with respect to the product requirements for 2021 and 2022, the payments for which will extend into 2023, and batches of adintrevimab drug product and certain services with respect to the product requirements for 2022, the payments for which will extend into 2023. There has been no material change to future minimum payments under non-cancelable purchase obligations associated with the Commercial Manufacturing Agreement. As of December 31, 2021, the Company paid $19.6 million under the Commercial Manufacturing Agreement. The $19.6 million payment resulted in a current prepaid expense of $16.6 million, included in prepaid expenses and other current assets, and a non-current prepaid expense of $3.0 million, included in other non-current assets, on the consolidated balance sheet.

Unless earlier terminated, the Commercial Manufacturing Agreement remains in effect for an initial period of five years and thereafter automatically renews for further successive periods of five years each. Either party may terminate the agreement upon the breach or default by the other party, other than a non-payment breach, that is not cured within 90 days after notice. Both parties are also entitled to terminate the Commercial Manufacturing Agreement if the other party becomes insolvent or is the subject of a petition in bankruptcy or of any other related proceeding or event. Either party may terminate either the Commercial Manufacturing Agreement in its entirety, or an individual order, (i) to the extent the other party suffers a force majeure event that is continuing for a predefined period of time and (ii) if the other party fails to make a payment when due under the arrangement and such non-payment is not cured within 30 days after notice.

As of December 31, 2021, the Company committed to minimum non-cancelable purchase obligations of $138.9 million related to batches of adintrevimab drug substance and $0.6 million related to certain services with respect to the product requirements for 2022, the payments for which will extend into 2023. Future minimum payments under non-cancelable

purchase obligations associated with the Commercial Manufacturing Agreement as of December 31, 2021 are expected to be as follows (in thousands):

Year Ending December 31,		
2022	$	75,599
2023		63,945
	$	139,544

Other Contracts

The Company has agreements with third parties that it enters into in the ordinary course of business for various products and services, including those related to research, preclinical and clinical operations, manufacturing and support. These contracts do not contain any material minimum purchase commitments. Certain of these agreements provide for termination rights subject to the payment of termination fees and/or wind-down costs. Under such agreements, the Company is contractually obligated to make certain payments to vendors upon early termination, primarily to reimburse them for their unrecoverable outlays incurred prior to cancellation as well as any amounts owed by the Company prior to early termination. The actual amounts the Company could pay in the future to the vendors under such agreements may differ from the purchase order amounts due to cancellation provisions. The termination fees were not probable of payment as of December 31, 2021 and 2020.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and estimated exposure amount. Legal fees and other costs associated with such proceedings are expensed as incurred. As of December 31, 2021 and 2020, the Company was not a party to any material legal proceedings.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to its vendors, lessors, contract research organizations, contract manufacturing organizations, business partners and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with members of its board of directors and its executive officers that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors or officers. The maximum potential amount of future payments that the Company could be required to make under these indemnification agreements is, in many cases, unlimited. As of December 31, 2021 and 2020, the Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

9. Convertible Preferred Stock

The Company has issued Series A convertible preferred stock (the "Series A Preferred Stock"), Series B convertible preferred stock (the "Series B Preferred Stock"), and Series C Preferred Stock (the "Series C Preferred Stock"), all of which are collectively referred to as the "Preferred Stock."

In July 2020, the Company issued and sold 6,237,500 shares of Series A Preferred Stock, at a price of $8.00 per share, for gross proceeds of $49.9 million and incurred $0.2 million of issuance costs. Concurrently, the Company issued 5,000,000 shares of Series A Preferred Stock to Adimab as consideration payable pursuant to the Adimab Assignment Agreement (see Note 7).

In October and November 2020, the Company issued and sold 1,410,434 shares of Series B Preferred Stock, at a price of $56.72 per share, for gross proceeds of $80.0 million and incurred $0.2 million of issuance costs. Adimab, a related party, participated in the Series B Preferred Stock financing by purchasing 44,076 shares of Series B Preferred Stock for an aggregate purchase price of $2.5 million. The issuance of the Series B Preferred Stock resulted in changes to certain terms of the Series A Preferred Stock. The Company concluded that such changes were not significant and resulted in a modification, rather than an extinguishment, of the Series A Preferred Stock. The changes to the terms of the Series A Preferred Stock did not result in incremental value to the stockholders. Therefore, there was no impact to the accounting for the Series A Preferred Stock.

In April 2021, the Company issued and sold 4,296,550 shares of its Series C Preferred Stock, at a price of $78.08578 per share, for aggregate gross proceeds of $335.5 million and incurred $0.3 million of issuance costs. Adimab, a related party, participated in the Series C Preferred Stock financing by purchasing 128,064 shares of Series C Preferred Stock for an aggregate purchase price of $10.0 million.

The terms of the Series C Preferred Stock are substantially the same as the terms of the Series A Preferred Stock and Series B Preferred Stock, except that the Original Issue Price per share and the Conversion Price per share of the Series C Preferred Stock is $78.08578.

In July 2021, the Company filed an amended and restated certificate of incorporation, which increased the Company's authority to issue (i) 150,000,000 shares of common stock and (ii) 16,944,484 shares of Preferred Stock. In August 2021, in connection with the closing of the IPO, the Company filed an amended and restated certificate of incorporation to, among other things: (i) increase the number of authorized shares of common stock from 150,000,000 shares to 1,000,000,000 shares, (ii) eliminate all references to the previously existing series of convertible preferred stock and (iii) authorize 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company's board of directors in one or more series.

Upon issuance of each series of Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance date of each series of Preferred Stock.

Upon the closing of the Company's IPO in August 2021, all shares of the Company's convertible preferred stock then outstanding converted into 84,722,420 shares of common stock (see Note 10). As of December 31, 2020, Preferred Stock consisted of the following (in thousands, except share amounts):

		December 31, 2020			
	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series A Preferred Stock	11,237,500	11,237,500	$ 89,706	$ 89,900	56,187,500
Series B Preferred Stock	1,410,434	1,410,434	79,842	80,000	7,052,170
	12,647,934	12,647,934	$ 169,548	$ 169,900	63,239,670

10. Common Stock

The voting, dividend and liquidation rights of the holders of shares of the Company's common stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above and described in the Company's final prospectus related to the IPO filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act on August 6, 2021.

In June 2020, the Company issued and sold 21,250,000 shares of its common stock to Adimab upon formation of the Company for $0.00002 per share. In July 2020, such shares of common stock were repurchased by the Company from Adimab contemporaneous with the execution of the Adimab Assignment Agreement, pursuant to which the Company acquired certain intellectual property rights in exchange for the issuance of 5,000,000 shares of its Series A Preferred Stock. As of December 31, 2021 the 21,250,000 shares of common stock repurchased from Adimab were retired and redesignated as authorized but unissued shares of the Company's common stock. As of December 31, 2020, the 21,250,000 shares of common stock repurchased from Adimab were recorded as treasury stock in the accompanying consolidated balance sheets and consolidated statements of convertible preferred stock and stockholders' equity (deficit) as such shares were not retired. The fair value of the repurchased common stock was $0.004 per share, or $85,000 in the aggregate, as determined based on a third-party valuation (see Note 7).

In April 2021, the Company increased the number of shares of common stock authorized for issuance from 19,000,000 to 23,251,555 shares and increased the number of shares of preferred stock authorized for issuance from 12,647,934 to 16,944,484 shares, of which 4,296,550 shares were designated as Series C Preferred Stock.

As described in Note 9 above, in July 2021, the Company filed an amended and restated certificate of incorporation, which increased the Company's authority to issue 150,000,000 shares of common stock. In August 2021, in connection with

the closing of the IPO, the Company filed an amended and restated certificate of incorporation to, among other things, increase the number of authorized shares of common stock from 150,000,000 shares to 1,000,000,000 shares.

As of December 31, 2021, the Company had reserved 36,886,646 shares of common stock for the exercise of outstanding stock options and the issuance of awards available for grant under the Company's 2020 Equity Incentive Plan, 2021 Equity Incentive Plan and 2021 Employee Stock Purchase Plan (see Note 11). As of December 31, 2020, the Company had reserved 80,466,735 shares of common stock for the potential conversion of shares of Preferred Stock into common stock, the exercise of outstanding stock options and the issuance of awards available for grant under the Company's 2020 Equity Incentive Plan (see Note 11).

Treasury Stock

In April and May 2021, the Company retired an aggregate of 22,600,000 shares of common stock held in treasury. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

In November 2021, the Company repurchased 468,751 shares of unvested restricted common stock at the original purchase price upon a termination of service during the vesting period. As of December 31, 2021, the shares of common stock repurchased were recorded as treasury stock in the accompanying consolidated balance sheets and consolidated statements of convertible preferred stock and stockholders' equity (deficit) as such shares were not retired. The fair value of the repurchased common stock was insignificant.

In February 2022, the Company repurchased 1,158,089 shares of unvested restricted common stock at the original purchase price upon a termination of service during the vesting period.

In March 2022, the Company retired an aggregate of 1,626,840 shares of common stock held in treasury. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

Stock Split

In July 2021, the Company effected a five-for-one stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 9). Accordingly, all share and per share amounts for all periods presented in the accompanying consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the Preferred Stock conversion ratios.

Initial Public Offering

In August 2021, the Company completed its IPO, pursuant to which it issued and sold 20,930,000 shares of its common stock, including 2,730,000 shares of its common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were approximately $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all of the shares of the Company's convertible preferred stock then outstanding converted into 84,722,420 shares of common stock. Upon the conversion of the convertible preferred stock, the Company reclassified the carrying value of the convertible preferred stock to common stock (at par value) and additional paid-in capital.

11. Stock-Based Compensation

2020 Equity Incentive Plan

The Company's 2020 Equity Incentive Plan (the "2020 Plan") provides for the Company to grant incentive stock options, non-qualified stock options, restricted stock awards, restricted stock units and other stock-based awards to employees, members of the board of directors and consultants. The 2020 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The board of directors may also delegate to one or more officers of the Company the power to grant awards to employees and certain officers of the Company. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee or any such officer if so delegated.

The exercise price for stock options granted may not be less than the fair market value of the Company's common stock on the date of grant, as determined by the board of directors, or at least 110% of the fair market value of the Company's

common stock on the date of grant in the case of an incentive stock option granted to an employee who owns stock representing more than 10% of the voting power of all classes of stock as determined by the board of directors as of the date of grant. Prior to the initial public offering, the Company's board of directors determined the fair value of the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant. Stock options granted under the 2020 Plan expire after ten years and typically vest over a four-year period with the first 25% vesting upon the first anniversary of a specified vesting commencement date and the remainder vesting in 36 equal monthly installments over the succeeding three years, contingent on the recipient's continued employment or service. Certain awards of stock options permit the holders to exercise the option in whole or in part prior to the full vesting of the option in exchange for unvested shares of restricted common stock with respect to any unvested portion of the option so exercised.

As of December 31, 2021, there were no shares authorized to be issued and no shares reserved for future issuance under the 2020 Plan. As of December 31, 2020, there were 22,820,305 shares authorized to be issued and 14,258,995 shares reserved for future issuance under the 2020 Plan.

2021 Equity Incentive Plan

In July 2021, the Company's board of directors adopted, and its stockholders approved, the 2021 Equity Incentive Plan (the "2021 Plan"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares reserved for issuance under the 2021 Plan was equal to 35,075,122, which is the sum of 11,413,572 new shares; plus the number of shares (not to exceed 23,661,550 shares), which represents (i) the number of shares that remained available for issuance under the 2020 Plan, at the time the 2021 Plan became effective, and (ii) any shares subject to outstanding stock options or other stock awards that were granted under the 2020 Plan that are forfeited, terminate, expire or are otherwise not issued. In addition, the number of shares of the Company's common stock reserved for issuance under the 2021 Plan will automatically increase on the first day of each calendar year, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 5% of the shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the board of directors. 5,539,145 shares of common stock were automatically added to the shares authorized for issuance under the 2021 Plan on January 1, 2022 pursuant to the terms of the 2021 Plan. 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, repurchased or are otherwise terminated by the Company under the 2021 Plan will be added back to the shares of common stock available for issuance under the 2021 Plan. As of December 31, 2021, there were 35,543,873 shares authorized to be issued, which includes 16,672,281 shares reserved for future issuance under the 2021 Plan.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. Prior to its initial public offering in August 2021, the Company historically had been a private company. Due to the proximity to the IPO, the Company continues to lack company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method. 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. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted:

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
Expected term (in years)	6.0	6.1
Expected volatility	73.3%	72.3%
Risk-free interest rate	1.0%	0.4%
Expected dividend yield	—%	—%

Stock Option Activity

The following table summarizes the Company's stock option activity since December 31, 2020:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
			(in years)	(in thousands)
Outstanding at December 31, 2020	2,968,070	$ 0.78	9.8	$ 11,362
Granted	16,249,689	11.76		
Forfeited	(346,167)	5.13		
Outstanding at December 31, 2021	18,871,592	$ 10.15	9.3	$ 24,897
Vested and expected to vest at December 31, 2021	18,871,592	$ 10.15	9.3	$ 24,897
Options exercisable at December 31, 2021	1,613,518	$ 2.74	8.6	$ 7,809

The weighted-average grant date fair value of stock options granted during the year ended December 31, 2021 and for period from June 3, 2020 (inception) to December 31, 2020 was $7.56 and $0.21, respectively, per share.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the estimated fair value of the Company's common stock for those stock options that had exercise prices lower than the estimated fair value of the Company's common stock at December 31, 2021 and 2020, as applicable. There were no options exercised during the year ended December 31, 2021. All stock options exercised during the period from June 3, 2020 (inception) to December 31, 2020 were made pursuant to awards that contain early-exercise provisions. The intrinsic value of the options that were exercised for the period from June 3, 2020 (inception) to December 31, 2020 was less than $0.1 million.

Early Exercise of Stock Options into Restricted Stock

The Company's restricted stock activity during the year ended December 31, 2021 is solely due to shares of restricted common stock issued pursuant to the permitted early exercise of stock options as permitted under the 2020 Plan prior to amendments. The 2021 Plan does not permit early exercise of stock options. Shares of common stock issued upon exercise of unvested stock options are restricted and continue to vest in accordance with the original vesting schedule applicable to the associated stock option award. The Company has the right to repurchase any unvested shares of restricted common stock, at the original purchase price, upon any voluntary or involuntary termination of the service relationship during the vesting period.

	Number of Shares
Unvested restricted stock at December 31, 2020	5,593,240
Issued	—
Vested	(2,042,314)
Repurchased	(468,751)
Unvested restricted stock at December 31, 2021	3,082,175

Proceeds from the early exercise of stock options are recorded as an early-exercise liability on the consolidated balance sheets. The liability for unvested common stock subject to repurchase is then reclassified to common stock and additional

paid-in capital as the Company's repurchase right lapses. Shares issued pursuant to the early exercise of stock options are not considered to be outstanding for accounting purposes until the shares vest. As of December 31, 2021 and 2020, the liability related to the payments for unvested shares from early-exercised options was less than $0.1 million.

In November 2021, the Company repurchased 468,751 shares of unvested restricted common stock for less than $0.1 million, which was recorded as a reduction of the early-exercise liability and as shares of treasury stock.

In February 2022, the Company repurchased 1,158,089 shares of unvested restricted common stock for less than $0.1 million, which was recorded as a reduction of the early-exercise liability and as shares of treasury stock.

In March 2022, the Company retired an aggregate of 1,626,840 shares of common stock held in treasury.

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense in the following expense categories of its consolidated statements of operations and comprehensive loss (in thousands):

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
Research and development	$ 6,591	$ 125
Selling, general and administrative	11,173	30
	$ 17,764	$ 155

As of December 31, 2021, total unrecognized stock-based compensation cost related to unvested awards was $105.9 million and the weighted-average period over which such expense is expected to be recognized is 3.3 years.

In February 2022, Tillman U. Gerngross, Ph.D. resigned as Chief Executive Officer and President and as a member of the Board of Directors. In accordance with his resignation, Dr. Gerngross's outstanding stock options were forfeited, resulting in a reversal of stock-based compensation expense of approximately $4.6 million which was recorded in the first quarter of 2022.

2021 Employee Stock Purchase Plan

In July 2021, the Company's board of directors adopted, and its stockholders approved, the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's initial public offering. A total of 1,342,773 shares of common stock were reserved for issuance under this plan. There were no shares issued under the 2021 ESPP as of December 31, 2021. The number of shares of common stock that may be issued under the 2021 ESPP will automatically increase on the first day of each calendar year, beginning on January 1, 2022 and continuing through January 1, 2031, by an amount equal to the lesser of (i) 1% of the shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, (ii) 2,685,546 shares and (iii) an amount determined by the Company's board of directors. The number of shares to be issued under the 2021 ESPP did not increase on January 1, 2022.

12. Income Taxes

During the year ended December 31, 2021 and for the period from June 3, 2020 (inception) to December 31, 2020, the Company did not record income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period, due to its uncertainty of realizing a benefit from those items. All of the Company's operating losses since inception have been generated in the United States.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
Federal statutory income tax rate	(21.0)%	(21.0)%
State income taxes, net of federal benefit	(2.9)	(0.4)
Federal research and development tax credits	(1.4)	(0.2)
Non-deductible expenses	—	12.9
Change in deferred tax asset valuation allowance	25.3	8.7
Effective income tax rate	—%	—%

The Company's net deferred tax assets consisted of the following (in thousands):

	December 31, 2021	December 31, 2020
Deferred tax assets:		
Net operating loss carryforwards	$ 51,635	$ 5,340
Research and development tax credits carryforwards	4,350	138
Stock-based compensation expense	4,116	31
Intangibles	1,707	—
Other	1,160	173
Total deferred tax assets	62,968	5,682
Valuation allowance	(62,968)	(5,682)
Net deferred tax assets	$ —	$ —

As of December 31, 2021 and 2020, the Company had U.S. federal NOL carryforwards of $221.9 million and $24.4 million, respectively, which may be available to reduce future taxable income. All of the U.S. federal NOL carryforwards have an indefinite carryforward period but are limited in their usage to 80% of annual taxable income. In addition, as of December 31, 2021, the Company had state NOL carryforwards of $81.9 million, which may be available to reduce future taxable income, of which $3.4 million have an indefinite carryforward period while the remaining $78.5 million begin to expire in 2041. As of December 31, 2021, the Company also had U.S. federal and state research and development tax credit carryforwards of $3.3 million and $1.3 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2041 and 2036, respectively.

Utilization of the U.S. federal and state NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. If a change in ownership were to have occurred during that period and resulted in the restriction of NOL or credit carryforwards, the reduction in the related deferred tax asset would be offset with a corresponding reduction in the valuation allowance.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative losses since inception, expectation of future losses and lack of other positive evidence and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2021 and 2020. Management reevaluates the positive and negative evidence at each reporting period. During the year ended December 31, 2021 and for the period from June 3, 2020 (inception) to December 31, 2020, the Company increased

its valuation allowance by $57.3 million and $5.7 million, respectively, with such increase recognized as income tax expense, in order to maintain a full valuation allowance against its deferred tax assets, and there were no changes recorded to the allowance during the period.

The Company assesses uncertain tax positions in accordance with the guidance for accounting for uncertain tax positions. This pronouncement prescribes a recognition threshold and measurement methodology for recording within the consolidated financial statements uncertain tax positions taken, or expected to be taken, in the Company's income tax returns. To the extent the uncertain tax positions do not meet the "more likely than not" threshold, the Company derecognizes such positions. For tax positions meeting the "more likely than not" threshold, the Company measures and records the highest probable benefit, and establishes appropriate reserves for benefits that exceed the amount likely to be sustained upon examination. As of December 31, 2021 and 2020, the Company has not recorded any uncertain tax positions or related interest and penalties.

The Company files income tax returns in the U.S. federal and various state jurisdictions and is not currently under examination by any taxing authority for any open tax year. Due to NOL carryforwards, all years remain open for income tax examination. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the federal or state tax authorities to the extent utilized in a future period. No federal or state tax audits are currently in process.

13. Defined Contribution Plan

The Company maintains a 401(k) Plan (the "401(k) Plan") for the benefit of eligible employees. The 401(k) Plan is a defined contribution plan under Section 401(k) of the Internal Revenue Code of 1986 that covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Pursuant to the terms of the 401(k) Plan, the Company is required to make non-elective contributions of 3% of eligible participants' compensation. For the year ended December 31, 2021 and the period from June 3, 2020 (inception) to December 31, 2020, the Company made contributions of $0.6 million and less than $0.1 million, respectively, to the 401(k) Plan.

14. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
Numerator:		
Net loss attributable to common stockholders	$ (226,790)	$ (65,319)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	42,621,265	3,608,491
Net loss per share attributable to common stockholders, basic and diluted	$ (5.32)	$ (18.10)

Shares of unvested restricted common stock are not considered outstanding for accounting purposes until vested and were excluded from the calculations of basic net loss per share attributable to common stockholders for all periods presented.

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of

diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	Year Ended December 31, 2021	Period from June 3, 2020 (Inception) to December 31, 2020
Convertible preferred stock (as converted to common stock)	—	63,239,670
Stock options to purchase common stock	18,871,592	2,968,070
Unvested restricted common stock	3,082,175	5,593,240
	21,953,767	71,800,980

15. Related Party Transactions

Adimab Assignment Agreement

Under the Adimab Assignment Agreement, Adimab, a principal stockholder of the Company, received upfront consideration in the form of Series A Preferred Stock, is entitled to receive milestone and royalty payments upon specified conditions, and receives payments from the Company for providing ongoing services under the agreement (see Note 7). Adimab participated in the Series B and C Preferred Stock financings by purchasing 44,076 and 128,064 shares of Series B and C Preferred Stock, respectively, for an aggregate purchase price of $2.5 million and $10.0 million, respectively (see Note 9).

During the year ended December 31, 2021, the Company recognized $7.5 million as IPR&D expense in connection with milestones payable under the Adimab Assignment Agreement. For the period from June 3, 2020 (inception) to December 31, 2020 the Company recognized $39.9 million as IPR&D expense in connection with the upfront consideration payable under the Adimab Assignment Agreement (see Note 7).

During the year ended December 31, 2021, the Company recognized $1.3 million of research and development expense, respectively, with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement. For the period from June 3, 2020 (inception) to December 31, 2020, the Company recognized $0.6 million of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement.

Adimab Collaboration Agreement

Under the Adimab Collaboration Agreement, the Company is obligated to pay Adimab for certain fees, milestone and royalty payments (see Note 7).

For the year ended December 31, 2021, the Company recognized $2.9 million of research and development expense under the Adimab Collaboration Agreement, which consisted of $2.6 million related to the quarterly fee (see Note 7) and $0.3 million related to services performed by Adimab on the Company's behalf.

As of December 31, 2021 and 2020, $0.6 million was due to Adimab under both the Adimab Assignment Agreement and the Adimab Collaboration Agreement by the Company. As of December 31, 2021 and 2020, no amounts were due from Adimab under the Adimab Assignment Agreement or the Adimab Collaboration Agreement to the Company.

16. Selected Quarterly Financial Data (unaudited)

The following table contains quarterly financial information for fiscal year 2021. The results for any quarter are not necessarily indicative of future period results.

	March 31, 2021	June 30, 2021	September 30, 2021	December 31, 2021
Quarter to date:	(1)	(2)		
Net loss	$ (38,700)	$ (44,673)	$ (60,375)	$ (83,042)
Net loss per share attributable to common stockholders, basic and diluted	$ —	$ (178.86)	$ (0.98)	$ (0.77)
Weighted-average common shares outstanding, basic and diluted	—	249,769	61,297,086	107,551,097
Year to date:	(1)	(2)		
Net loss	$ (38,700)	$ (83,373)	$ (143,748)	$ (226,790)
Net loss per share attributable to common stockholders, basic and diluted	$ —	$ (663.94)	$ (7.06)	$ (5.32)
Weighted-average common shares outstanding, basic and diluted	—	125,574	20,346,771	42,621,265

(1) Net loss per share data is not applicable for the three months ended March 31, 2021 as the Company had no shares of common stock outstanding for accounting purposes during that period. All of the 5,593,240 shares of common stock issued and outstanding as of March 31, 2021 were shares of unvested restricted common stock issued by the Company upon the early exercise of stock options granted in June 2020. As a result, such shares are not considered outstanding for accounting purposes until vested and were excluded from the calculations of basic net loss per share attributable to common stockholders for the three months ended March 31, 2021.

(2) The June 30, 2021 Quarterly Report on Form 10-Q filed with the SEC on September 20, 2021 included a clerical error. The net loss numbers used in the basic and diluted share computation for the three and six months ended June 30, 2021 were in thousands, resulting in a basic and diluted loss per share of $0.18 and $0.66, respectively. The corrected net loss number to be used in the basic and diluted share computation for the three and six months ended June 30, 2021 should have been the net loss multiplied by one thousand, resulting in a corrected basic and diluted loss per share of $178.86 and $663.94, respectively. This correction is reflected in the above table. This error had no impact to the reported amount of net loss or the unaudited consolidated balance sheets, statements of cash flows, or statements of stockholders' equity (deficit), and notes to the financial statements as of, and for the three and six months ended June 30, 2021, other than to Note 13. Net Loss per Share. The materiality of the error was assessed in accordance with the SEC's Staff Accounting Bulletin 99 and the Company concluded that the previously issued consolidated financial statements were not materially misstated. In accordance with the SEC's Staff Accounting Bulletin 108, this immaterial error will be corrected and the revision will be presented prospectively here and in future filings.

Exhibit 4.2

DESCRIPTION OF ADAGIO THERAPEUTICS, INC. COMMON STOCK

The following description of the common stock of Adagio Therapeutics, Inc., or the Company, and certain provisions of the Company's amended and restated certificate of incorporation, or the Restated Certificate, and amended and restated bylaws, or the Bylaws, are summaries. These summaries are qualified in their entirety by reference to the provisions of the General Corporation Law of the State of Delaware and the complete texts of the Restated Certificate and the Bylaws, which are incorporated by reference as Exhibits 3.1 and 3.2, respectively, of the Company's Annual Report on Form 10-K to which this description is also an exhibit.

General

The Restated Certificate authorizes the Company to issue up to 1,000,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share, all of which shares of preferred stock are undesignated. The Company's board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock

Voting Rights

Each holder of the Company's common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. The affirmative vote of holders of at least 66 ⅔% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, is required to amend certain provisions of the Restated Certificate, including provisions relating to amending the Company's Bylaws, the classified board, the size of the Company's board, removal of directors, director liability, vacancies on the Company's board, special meetings, stockholder notices, actions by written consent and exclusive forum.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

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

Rights and Preferences

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

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

The Company is subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that 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 began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 ⅔% of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a "business combination" to include the following:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;

- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of 10% or more of the assets of the corporation or of any direct or indirect majority-owned subsidiary involving the interested stockholder (in one transaction or a series of transactions);

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;

- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation or any such subsidiary beneficially owned by the interested stockholder; or

- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an "interested stockholder" as an entity or person who, together with the person's affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, 15% or more of the outstanding voting stock of the corporation.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

The Restated Certificate and the Bylaws provide for the Company's board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of the Company's stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because the Company's stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding are able to elect all of the Company's directors. The Restated Certificate and the Bylaws provide that directors may be removed by the stockholders only for cause upon the vote of at least 66 ⅔% of the voting power of all of the then-outstanding shares of capital stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board and subject to the rights of any series

of then-outstanding Preferred Stock, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

The Restated Certificate and the Bylaws also provide that all stockholder actions must be effected at a duly called meeting of stockholders and eliminate the right of stockholders to act by written consent without a meeting. The Bylaws provide that only the chairman of the board of directors, the chief executive officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

The Bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing and specify requirements as to the form and content of a stockholder's notice.

The Restated Certificate and the Bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of at least 66 ⅔% of the voting power of all of the then-outstanding shares of capital stock.

The Restated Certificate gives the Company's board of directors the authority, without further action by the Company's stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control.

The combination of these provisions makes it more difficult for the Company's existing stockholders to replace the Company's board of directors as well as for another party to obtain control of the Company by replacing the Company's board of directors. Since the Company's board of directors has the power to retain and discharge the Company's officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the Company's board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of the Company.

These provisions are intended to enhance the likelihood of continued stability in the composition of the Company's board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce the Company's vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for the Company's shares and may have the effect of delaying changes in the Company's control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of the Company's stock that could result from actual or rumored takeover attempts. The Company believes that the benefits of these provisions, including increased protection of the Company's potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure the Company's company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Exhibit 10.5

Adagio Therapeutics, Inc.

Non-Employee Director Compensation Policy

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Adagio Therapeutics, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service upon and following the date of the underwriting agreement between the Company and the underwriters managing the initial public offering of the Company's common stock (the "***Common Stock***"), pursuant to which the Common Stock is priced in such initial public offering (the "***Effective Date***"). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy is effective as of the Effective Date and may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal quarter, with the pro-rated amount paid on the last day of the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
    a. All Eligible Directors: $40,000
    b. Independent Chair of the Board Service Retainer (in addition to Eligible Director Service Retainer): $30,000

2. Annual Committee Chair Service Retainer:
    a. Chair of the Audit Committee: $15,000
    b. Chair of the Compensation Committee: $10,000
    c. Chair of the Nominating and Corporate Governance Committee: $8,000

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
    a. Member of the Audit Committee: $7,500
    b. Member of the Compensation Committee: $5,000
    c. Member of the Nominating and Corporate Governance Committee: $4,000

Expenses

The Company will reimburse Eligible Directors for ordinary, necessary and reasonable out-of-pocket travel expenses to cover in-person attendance at and participation in Board and committee meetings; provided, that the Eligible Director timely submit to the Company appropriate documentation substantiating such expenses in accordance with the Company's travel and expense policy, as in effect from time to time.

Equity Compensation

The equity compensation set forth below will be granted under the Company's 2021 Equity Incentive Plan (the "***Plan***"), subject to the approval of the Plan by the Company's stockholders. All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying Common Stock on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grants: For each Eligible Director who is first elected or appointed to the Board following the Effective Date, on the date of such Eligible Director's initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase shares of Common Stock with an aggregate Black-Scholes grant date value of $800,000 (the "***Initial Grant***"); provided, that, in no event shall the number of shares subject to the Initial Grant exceed 150,000 shares. The shares subject to each Initial Grant will vest over a three-year period, with one-third of the shares subject to the Initial Grant vesting on the first anniversary of the grant date and 1/36th of the shares subject to the Initial Grant vesting in equal monthly installments thereafter, such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director's Continuous Service (as defined in the Plan) through each such vesting date, and will vest in full upon a Change in Control (as defined in the Plan), subject to the Eligible Director's Continuous Service through such date.

2. Annual Grants: On the date of each annual stockholder meeting of the Company held after the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholder meeting (excluding any Eligible Director who is first appointed or elected by the Board at such meeting) will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase shares of Common Stock with an aggregate Black-Scholes grant date fair value of $400,000 (the "***Annual Grant***"); provided, that, in no event shall the number of shares subject to the Annual Grant exceed 75,000 shares. The shares subject to the Annual Grant will vest in full on the first anniversary of the date of grant, subject to the Eligible Director's Continuous Service through such vesting date; provided, that the Annual Grant will in any case be fully vested on the date of Company's next annual stockholder meeting, subject to the Eligible Director's Continuous Service through such vesting date; provided, further, that the Annual Grant will vest in full upon a Change in Control, subject to the Eligible Director's Continuous Service through such date. With respect to an Eligible Director who, following the Effective Date, was first elected or appointed to the Board on a date other than the date of the Company's annual stockholder meeting, upon the Company's first annual stockholder meeting following such Eligible Director's first joining the Board, such Eligible Director's first Annual Grant will be pro-rated to reflect the time between such Eligible Director's election or appointment date and the date of such first annual stockholder meeting.

Non-Employee Director Compensation Limit

Notwithstanding the foregoing, the aggregate value of all compensation granted or paid, as applicable, to any individual for service as a Non-Employee Director (as defined in the Plan) shall in no event exceed the limits set forth in Section 3(d) of the Plan.

Exhibit 10.10

FIRST AMENDMENT TO THE AMENDED AND RESTATED EMPLOYMENT AGREEMENT OF DAVID HERING

This First Amendment to the Amended and Restated Employment Agreement of David Hering (the "***Amendment***") is entered into this 23rd day of February 2022 (the "***Amendment Effective Date***"), by and between David Hering (the "***Executive***") and **Adagio Therapeutics, Inc.** (the "***Company***").

Recitals

WHEREAS, the Company and the Executive have entered into that certain Amended and Restated Employment Agreement dated August 5, 2021 (the "***Executive Agreement***"); and

WHEREAS, the Company desires to continue to employ Executive as its Chief Operating Officer and to employ the Executive as its Interim Chief Executive Officer and the Executive desires to accept such employment and to perform the duties to the Company on the terms and conditions hereinafter set forth in this Amendment; and

WHEREAS, the Company and the Executive wish to amend the Executive Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other valid consideration, the sufficiency of which is acknowledged, the parties hereto agree as follows:

Agreement

1. **Amendment to Section 1(b).** Section 1(b) of the Executive Agreement is hereby amended by replacing the first paragraph in Section 1(b) in its entirety with the following:

> The Executive shall serve as the Chief Operating Officer of the Company and shall have such powers and duties as customarily associated with the office of Chief Operating Officer, and as may from time to time be prescribed by the Chief Executive Officer of the Company (the "CEO"), subject to the direction and control of the CEO. In his service as Chief Operating Officer, the Executive shall report to the CEO.
>
> As of February 23, 2022 (the "***Amendment Effective Date***"), the Executive shall additionally serve as the Interim Chief Executive Officer of the Company and shall have such powers and duties as customarily associated with the office of Interim Chief Executive Officer, and as may from time to time be prescribed by the Board of Directors of the Company (the "***Board***"), subject to the direction and control of the Board. In his service as Interim Chief Executive Officer, the Executive shall report to the Board.

2. **Amendment to Section 1(c).** Section 1(c) of the Executive Agreement is hereby amended by replacing the second paragraph in Section 1(c) in its entirety with the following:

The Executive agrees not to engage actively in any other employment, occupation, or consulting activity for any direct or indirect remuneration without the prior approval of the CEO (or the Board, if while serving as Interim Chief Executive Officer); provided, however, that Executive may, without such approval, serve in any capacity with any civic, educational, or charitable organization, participate in industry affairs and manage Executive's family's personal passive investments, and engage in the activities set forth in Appendix A to this Agreement, provided that in each case such services do not materially interfere with Executive's obligations to the Company, create a conflict of interest, violate any of the Executive's Continuing Obligations (as defined in Section 9 below) or cause any reputational damage to the Company as reasonably determined by the Board.

3. Amendment to Section 2.

a. Section 2(a) is hereby replaced in its entirety as follows:

Base Salary. The Company will continue to pay Executive, as compensation for the performance of the Executive's duties and obligations hereunder, salary at the rate of $510,000 per year, less applicable deductions. The Executive's salary shall be subject to annual review not later than March 31st of each year for possible increase by the Board or the Compensation Committee of the Board (the "***Compensation Committee***"), which may be adjusted from time to time. The base salary in effect at any given time is referred to herein as "***Base Salary***." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for its executive officers. As of the Amendment Effective Date, and while Executive serves as Interim Chief Executive Officer, Executive shall receive a monthly stipend of $7,500, less applicable deductions.

b. Section 2(b) is hereby amended by inserting the following sentence immediately following the end of the third sentence in Section 2(b):

Subject to the foregoing, as of the Amendment Effective Date and while Executive serves as Interim Chief Executive Officer, the Target Bonus will be sixty percent (60%) of the Base Salary. For the calendar year 2022, the Annual Bonus shall be calculated as follows: (i) for the period during which Executive serves only as Chief Operating Officer, the Target Bonus will be forty percent (40%) of Executive's actual base salary for the calendar year 2022; and (ii) for the period during which Executive serves as Interim Chief Executive Officer, the Target Bonus will be sixty percent (60%) of an assumed base salary of $600,000.

4. The Company and the Executive further agree that this Amendment does not constitute grounds for "Good Reason" pursuant to Section 3(e) of the Executive Agreement, or otherwise constitute any trigger for the Company's payment of any severance benefits to Executive pursuant to the Executive Agreement. The Company and Executive further agree that Executive's title of Interim Chief Executive Officer is temporary, and neither the removal of the Interim Chief Executive Officer title, nor the diminution of the interim related duties, will constitute grounds for "Good Reason" pursuant to Section 3(e) of the Executive Agreement.

5. Except as modified or amended in this Amendment, no other term or provision of the Executive Agreement is amended or modified in any respect. Executive remains employed "at will." The Executive Agreement and its exhibits, the Employee Proprietary Information and Inventions Assignment Agreement, and this Amendment, set forth the entire understanding between the parties with regard to the subject matter hereof and supersedes any prior oral discussions or written communications and agreements. This Amendment cannot be modified or amended except in writing signed by the Executive and an authorized officer of the Company.

The parties have executed this First Amendment to the Amended and Restated Employment Agreement of David Hering on the day and year first written above.

Adagio Therapeutics, Inc.

/s/ René Russo

_____

René Russo
Chairperson of the Board of Directors

Executive

/s/ David Hering

_____

David Hering

I hereby acknowledge and reaffirm my obligations pursuant to the Employee Proprietary Information and Inventions Assignment Agreement.

/s/ David Hering

_____

David Hering

Date: 3/25/2022

Exhibit 10.11

EMPLOYMENT AGREEMENT

This Employment Agreement ("***Agreement***") is made between Adagio Therapeutics, Inc., a Delaware corporation (the "***Company***"), and Jill Andersen (the "***Executive***"), this 24th day of September 2021.

WHEREAS, the Company desires for Executive to provide services to the Company, and wishes to provide Executive with certain compensation and benefits in return for such employment services, and Executive wishes to be employed by the Company and to provide personal services to the Company in return for certain compensation and benefits; and

WHEREAS, the Company and Executive desire to enter into this Agreement, effective as of November 1, 2021 (the "***Effective Date***").

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. Employment.

(a) Term. The Company shall employ the Executive and the Executive shall be employed by the Company pursuant to this Agreement commencing as of the Effective Date and continuing until such employment is terminated in accordance with the provisions hereof (the "***Term***"). The Executive's employment with the Company shall continue to be "at will," meaning that the Executive's employment may be terminated by the Company or the Executive at any time and for any reason subject to the terms of this Agreement.

(b) Position and Duties.

The Executive shall serve as the Chief Legal Officer of the Company and shall have such powers and duties as customarily associated with the office of Chief Legal Officer, and as may from time to time be prescribed by the Chief Executive Officer of the Company (the "***CEO***"), subject to the direction and control of the CEO. The Executive shall report to the CEO.

Nothing in this Agreement shall prohibit the Executive from reasonably delegating parts of the responsibilities set forth in or contemplated by this Section 1(b) to other employees of the Company or its subsidiaries. Upon the termination of Executive's service for any reason, unless otherwise determined by the Company's Board of Directors (the "***Board***"), Executive will be deemed to have resigned from any other positions held at the Company or any of its subsidiaries or affiliates voluntarily, without any further required action by Executive, as of the cessation of Executive's services, and Executive, at the Board's request, will execute any documents deemed in the discretion of the Company to be reasonably necessary to reflect Executive's resignation(s).

(c) Outside Activities. Executive will use good faith efforts to discharge Executive's obligations under this Agreement to the best of Executive's ability. Executive will devote substantially all of Executive's business efforts and time to the Company.

The Executive agrees not to engage actively in any other employment, occupation, or consulting activity for any direct or indirect remuneration without the prior approval of the CEO; provided, however, that Executive may, without such approval, serve in any capacity with any civic, educational, or charitable organization, participate in industry affairs and manage Executive's family's personal passive investments, and engage in the activities set forth in Appendix A to this Agreement, provided that in each case such services do not materially interfere with Executive's obligations to the Company, create a conflict of interest, violate any of the Executive's Continuing Obligations (as defined in Section 9 below) or cause any reputational damage to the Company as reasonably determined by the Board.

The Executive may retain any compensation or benefits received as a result of consented to service as a director without any offset in respect of any compensation or benefits to be provided hereunder.

2. Compensation and Related Matters. This Section 2 sets forth the compensation and benefits to be provided to the Executive during the Term.

(a) Base Salary. The Executive will continue to pay Executive, as compensation for the performance of the Executive's duties and obligations hereunder, salary at the rate of $400,000 per year. The Executive's salary shall be subject to annual review not later than March 31st of each year for possible increase by the Board or the Compensation Committee of the Board (the "***Compensation Committee***"), which may be adjusted from time to time. The base salary in effect at any given time is referred to herein as "***Base Salary***." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for its executive officers

(b) Incentive Compensation. The Executive shall participate in an annual cash incentive compensation plan (the "***Annual Bonus Plan***"). The Executive will be eligible to earn an annual bonus for each full calendar year completed (the "***Annual Bonus***"). The Executive's target Annual Bonus will be forty percent (40%) of Executive's Base Salary (the "***Target Bonus***") based on Base Salary in effect on January 1st of the applicable performance period. The actual Annual Bonus payable to the Executive with respect to a performance period will be determined by the Compensation Committee based on achieving performance goals and objectives for such calendar year as reasonably determined by the Compensation Committee. The Executive's Annual Bonus shall be paid as soon as administratively practicable after the end of the performance period, but in no event later than the March 15th immediately following such period; provided, that the Executive must remain continuously employed by the Company through the date on which the Board approves the actual Annual Bonus amount payable to the Executive to be eligible to receive bonus (except as otherwise provided in Section 4(c) or 5(a)). For the calendar year 2021, no pro-rated Annual Bonus shall be provided.

(c) Option Award. Subject to approval by the Board (or any authorized committee thereof), the Company shall grant the Executive an option (the "***Option***") to purchase 514,863 shares of the Company's common stock, with an exercise price equal to the fair market value of a share of the Company's common stock on the grant date, as determined by the Board (or any authorized committee thereof), pursuant to the terms and conditions of the Company's 2021 Equity Incentive Plan (the "***Plan***") and the applicable stock option grant notice and stock

option agreement to be provided to Executive (together with the Plan, the "***Equity Documents***"); provided, however, and notwithstanding anything to the contrary in the Equity Documents, Section 5 and Section 6 of this Agreement, as applicable, shall apply in the event of a termination by the Company without Cause or by the Executive for Good Reason (as such terms are defined below). Except as otherwise provided in this Agreement, the Option will vest subject to the terms and conditions of the Equity Documents, with 25% of the shares subject to the Option vesting upon the first anniversary of the Effective Date and the remaining 75% of the shares subject to the Option vesting over the subsequent 3-year period in substantially equal monthly installments at a rate of 1/48th of the total shares subject to the Option each month, subject to the Executive's continuous service to the Company as of each such vesting date. Notwithstanding anything to the contrary in the Equity Documents, the definition of "Cause" provided in Section 3(c) of this Agreement shall apply to the Equity Documents and to any future equity awards that may be granted to the Executive in lieu of any definition of "Cause" provided under the applicable equity award documents.

(d) Expenses. The Company shall promptly pay or reimburse the Executive for all reasonable expenses incurred by the Executive while performing services hereunder, including but not limited to travel expenses and attendance at industry events, in accordance with the policies and procedures then in effect and established by the Company for its executive officers, but in no event later than thirty (30) days submission of a reimbursement request in accordance with such policies or procedures.

(e) Other Benefits. The Executive shall be eligible to participate in or receive benefits under the Company's employee benefit plans in effect from time to time, subject to the terms of such plans.

(f) Paid Time Off. The Executive shall be entitled to take paid time off in accordance with the Company's applicable paid time off policy for executives, as may be in effect from time to time.

(g) Stock Ownership Guidelines. The Executive shall be subject to the Company's Executive Stock Ownership Guidelines while providing services under this Agreement.

(h) Treatment of Equity Awards upon a Change in Control. The following provisions shall apply to any award granted under the Plan or any other plan, agreement or arrangement based on the value of a share of the Company's common stock on or after the Effective Date (collectively, the "***Equity Awards***") to the extent the Equity Awards are assumed, continued or substituted by the surviving or acquiring entity (or its parent) in connection with a Change in Control (as defined in the Plan) and the Executive continues to provide services to the Company or its successor following such Change in Control:

(i) Except as otherwise provided in the Change in Control transaction's definitive agreement, the Plan or the applicable award agreement, or as set forth in Section 6 below, Equity Awards subject to vesting solely on account of completing periods of covered employment or service (collectively, the "***Time-Based***

Equity Awards") shall not immediately accelerate and become fully vested and exercisable or non-forfeitable on such a Change in Control, and

(ii) all other Equity Awards, including but not limited to performance stock units vesting based on achieving pre-established performance goals (collectively, the "***Performance-Based Equity Awards***") shall be governed by the terms of the Plan and the applicable award agreement.

3. Termination. The Executive's employment hereunder may be terminated without any breach of this Agreement under the following circumstances:

(a) Death. The Executive's employment hereunder shall terminate upon death.

(b) Disability. The Company may terminate the Executive's employment if the Executive is disabled and unable to perform or expected to be unable to perform the essential functions of the Executive's then existing position or positions under this Agreement with or without reasonable accommodation for a period of 180 days (which need not be consecutive) in any 12-month period. If any question shall arise as to whether during any period the Executive is disabled so as to be unable to perform the essential functions of the Executive's then existing position or positions with or without reasonable accommodation, the Executive may, and at the request of the Company shall, submit to the Company a certification in reasonable detail by a physician selected by the Company to whom the Executive or the Executive's guardian has no reasonable objection as to whether the Executive is so disabled or how long such disability is expected to continue, and such certification shall for the purposes of this Agreement be conclusive of the issue. The Executive shall cooperate with any reasonable request of the physician in connection with such certification. If such question shall arise and the Executive shall fail to submit such certification, the Company's determination of such issue shall be binding on the Executive. Nothing in this Section 3(b) shall be construed to waive the Executive's rights, if any, under existing law including, without limitation, the Family and Medical Leave Act of 1993, 29 U.S.C. §2601 *et seq*. and the Americans with Disabilities Act, 42 U.S.C. §12101 *et seq.*

(c) Termination by the Company for Cause. The Company may terminate the Executive's employment hereunder for Cause. For purposes of this Agreement, "***Cause***" shall mean any of the following:

(i) the Executive's unauthorized use or disclosure of confidential information or trade secrets of the Company for Executive's benefit or any material breach of a written agreement between the Executive and the Company, including without limitation a material breach of this Agreement or the Restrictive Covenants Agreement;

(ii) the Executive's conviction of, or pleading no contest to, a felony under the laws of the United States or any state thereof (other than in connection with a traffic violation that does not result in imprisonment) or any crime that results in the Executive's incarceration in a federal, state, or local jail or prison;

(iii) the Executive's material and willful misconduct in the performance of the Executive's duties or the Executive's willful or repeated failure or refusal to substantially perform assigned duties (other than any such failure of refusal resulting from the Executive's incapacity due to physical or mental illness or any such actual or anticipated failure after the issuance of a notice of Good Reason by the Executive pursuant to Section 3(e) hereof), in any case, which willful misconduct, failure or refusal has continued for more than thirty (30) days following written notice from the CEO of such willful misconduct, failure or refusal;

(iv) any act of fraud, embezzlement or material misappropriation committed by the Executive against the Company (other than good faith expense account disputes);

(v) willful engaging by the Executive in any act that brings the Company into public disrepute or disgrace or causes material harm to the customer relations, operations or business prospects of the Company; or

(vi) the Executive's failure to cooperate with a bona fide internal investigation or an investigation by regulatory or law enforcement authorities, after being instructed by the Company to cooperate, or the willful destruction or failure to preserve documents or other materials known to be relevant to such investigation or the inducement of others to fail to cooperate or to produce documents or other materials in connection with such investigation.

For purposes of this Section 3(c), no act, or failure to act, on the Executive's part shall be deemed "willful" if done, or omitted to be done, by the Executive in good faith and with reasonable belief that the Executive's act, or failure to act, was in the best interest of the Company.

In the case of any termination for Cause, the Company shall provide written notice to the Executive setting forth to a reasonable extent at least the principal acts or omissions of the Executive giving rise to Cause for termination. It is agreed to by the parties that the below par or below average financial performance of the Company and/or its subsidiaries, in and of itself shall not constitute Cause for employment termination under this Agreement.

A termination for Cause under this Section 3(c) (other than with respect to Section 3(c)(ii) shall in no event become effective under the Agreement unless the provisions of this paragraph are complied with. The Executive must be given written notice by the Board of the intention to terminate Executive's employment for Cause, such notice (A) to state in detail the act or acts or failure or failures to act that constitute the grounds on which the proposed termination for Cause is based and (B) to be given within three (3) months of the Board learning of such act or acts or failure or failures to act. The Executive shall have ten (10) days after the date that such written notice has been given to the Executive in which to cure such conduct, to the extent such cure is possible. If the Executive fails to cure such conduct, the Executive shall thereupon be terminated for Cause.

(d) Termination by the Company without Cause. The Company may terminate the Executive's employment hereunder at any time without Cause. Any termination by the Company of the Executive's employment under this Agreement which does not constitute a termination for Cause under Section 3(c) and does not result from the death or disability of the Executive under Section 3(a) or 3(b) shall be deemed a termination without Cause.

(e) Termination by the Executive. The Executive may terminate employment hereunder at any time for any reason, including but not limited to, Good Reason. For purposes of this Agreement, "***Good Reason***" shall mean that the Executive has completed all steps of the Good Reason Process (hereinafter defined) following the occurrence of any of the following events without the Executive's consent (each, a "***Good Reason Condition***"):

(i) a material diminution in the Executive's title, responsibilities, authority or duties; or a material reduction in the authority, duties, or responsibilities of the CEO to whom the Executive is required to report;

(ii) a Change in Control following which either: (A) there is a material reduction in the budget over which the Executive retains authority or (B) the Executive is not Chief Legal Officer of the Company or, if the Company becomes a subsidiary of one or more entities following the Change in Control, the post-consummation ultimate parent entity of the Company; or

(iii) a material breach of this Agreement by the Company, including without limitation, a reduction of the Executive's Base Salary or Target Bonus in violation of Section 2(a) or 2(b) (except for across-the-board salary reductions of not more than ten percent (10%) similarly affecting all or substantially all senior management employees of the Company), a relocation of the Executive's place of employment to any location that is greater than twenty (20) miles from the Executive's home office, or the failure of the Company to obtain the assumption in writing of the Company's obligations to the Executive under this Agreement by any successor as required under Section 13 below.

(f) Good Reason Process. The "***Good Reason Process***" consists of the following steps:

(i) the Executive reasonably determines in good faith that a Good Reason Condition has occurred;

(ii) the Executive notifies the Company in writing of the first occurrence of the Good Reason Condition within sixty (60) days of the first occurrence of such condition;

(iii) the Executive cooperates in good faith with the Company's efforts, for a period of not less than thirty (30) days following such notice (the "***Cure Period***"), to remedy the Good Reason Condition;

(iv) notwithstanding such efforts, the Good Reason Condition continues to exist at the end of the Cure Period; and

(v) the Executive terminates employment within sixty (60) days after the end of the Cure Period.

If the Company cures the Good Reason Condition during the Cure Period, Good Reason shall be deemed not to have occurred.

4. Matters Related to Termination.

(a) Notice of Termination. Except for termination as specified in Section 3(a), any termination of the Executive's employment by the Company or any such termination by the Executive shall be communicated by written Notice of Termination to the other party hereto. For purposes of this Agreement, a "***Notice of Termination***" shall mean a notice which shall indicate the specific termination provision in this Agreement relied upon.

(b) Date of Termination. "***Date of Termination***" shall mean: (i) if the Executive's employment is terminated by death, the date of death; (ii) if the Executive's employment is terminated on account of disability under Section 3(b) or by the Company for Cause under Section 3(c), the date on which Notice of Termination is given; (iii) if the Executive's employment is terminated by the Company without Cause under Section 3(d), thirty (30) days after the date on which a Notice of Termination is given or a later date otherwise specified by the Company in the Notice of Termination; (iv) if the Executive's employment is terminated by the Executive under Section 3(e) other than for Good Reason, thirty (30) days after the date on which a Notice of Termination is given, and (v) if the Executive's employment is terminated by the Executive under Section 3(e) for Good Reason, the date on which a Notice of Termination is given after the end of the Cure Period. Notwithstanding the foregoing, in the event that the Executive gives a Notice of Termination to the Company, the Company may unilaterally accelerate the Date of Termination and such acceleration shall not result in a termination by the Company for purposes of this Agreement.

(c) Accrued Obligations. If the Executive's employment with the Company is terminated for any reason, the Company shall pay or provide to the Executive (or to the Executive's authorized representative or estate) (i) any Base Salary earned through the Date of Termination; (ii) unpaid expense reimbursements (subject to, and in accordance with, Section 2(c) of this Agreement); and (iii) any vested benefits the Executive may have under any employee benefit plan or compensation arrangement of the Company (including equity compensation plans and insurance coverages) through the Date of Termination, which vested benefits shall be paid and/or provided in accordance with the terms of such employee benefit plans. In the event that the Executive terminates employment due to death or Disability (as defined in Section 3(b) above), the Executive (or in the case of death, the Executive's estate) shall be entitled to receive the Earned Bonus (as defined in Section 5(a)) at the same time bonuses are paid to other employees who are actively employed by the Company. The amounts described under this Section 4(c) are referred to below as the "***Accrued Obligations***."

(d) Resignation of All Other Positions. To the extent applicable, the Executive shall be deemed to have resigned from all officer and board member positions that the Executive holds with the Company or any of its respective subsidiaries and affiliates upon the termination

of the Executive's employment for any reason. The Executive shall execute any documents in reasonable form as may be requested to confirm or effectuate any such resignations.

5. Severance Pay and Benefits Upon Termination by the Company without Cause or by the Executive for Good Reason. If the Executive's employment is terminated by the Company without Cause as provided in Section 3(d), or the Executive terminates employment for Good Reason as provided in Section 3(e), then, in addition to the Accrued Obligations, and subject to (i) the Executive signing a separation agreement and release in a form substantially the same as set forth in Appendix B (the "***Separation Agreement***"), which provides that if the Executive materially breaches any of the Continuing Obligations, all payments of the Severance Amount shall immediately cease, and (ii) the Separation Agreement becoming irrevocable, all within sixty (60) days after the Date of Termination (or such shorter period as set forth in the Separation Agreement):

(a) Cash Severance. The Company shall pay the Executive an amount equal to nine (9) months' of the Executive's Base Salary (the "***Severance Amount***") and, in the event that the Executive's employment is terminated after the end of the calendar year but prior to the payment of any Annual Bonus for the immediately preceding calendar year, the Executive shall be entitled to receive a lump sum payment of any unpaid Annual Bonus earned based on achievement of the applicable performance goals and objectives, without any reduction for individual performance, with respect to such immediately preceding calendar year (the "***Earned Bonus***").

(b) COBRA Premiums. Subject to the Executive's copayment of premium amounts at the applicable active employees' rate and the Executive's proper election to receive benefits under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("***COBRA***"), the Company shall pay to the group health plan provider or the COBRA provider a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company until the earliest of (A) the nine (9) month anniversary of the Date of Termination; (B) the date that the Executive becomes eligible for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of the Executive's health continuation rights under COBRA; provided, however, that if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments to the Executive shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

(c) Delayed Forfeiture of Time-Based Equity Awards. Notwithstanding anything to the contrary in any Time-Based Equity Awards, if the Separation Agreement becomes effective, the unvested portions of all Time-Based Equity Awards shall not terminate or be forfeited on the Date of Termination, but rather shall remain outstanding until 3 months after the Date of Termination (the "***Pre-CIC Protection Period***"). If the Company has not, prior to the end of the Pre-CIC Protection Period, entered into a definitive agreement that, if closed, would result in a Change in Control (a "***P&S Agreement***"), then the unvested portion of the

Time-Based Equity Awards shall terminate and be forfeited. If the Company, prior the end of the Pre-CIC Protection Period, enters into a P&S Agreement, then the Time-Based Equity Awards shall remain outstanding and become fully vested upon a Change in Control resulting from such agreement. Time-Based Equity Awards shall terminate and be forfeited if the Company abandons a sale of the Company as contemplated under the P&S Agreement entered into during the Pre-CIC Protection Period. No additional vesting of the Time-Based Equity Awards shall occur following the Date of Termination except on account of a Change in Control during or after the Pre-CIC Protection Period as specifically provided above. For the avoidance of doubt, any unvested Performance-Based Equity Awards shall terminate and be forfeited on the Date of Termination unless otherwise provided by the terms of the Plan or the applicable award agreement.

(d) Severance Payment Timing. The amounts payable under Section 5 (other than the Earned Bonus, as applicable), to the extent taxable, shall be paid or commence to be paid within thirty (30) days after the Date of Termination (or such longer period as required in order to have an enforceable release, but in no event later than sixty (60) days after the Date of Termination); provided, however, that if the period applicable to Executive's termination of employment begins in one calendar year and ends in a second calendar year, such payments to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"), shall be paid or commence to be paid in the second calendar year by the last day of such period. The Severance Amount shall be paid in a single lump sum and the Earned Bonus, if any, shall be paid at the same time as if the Executive had remained employed with the Company through the payment date.

6. Severance Pay and Benefits Upon Termination by the Company without Cause or by the Executive for Good Reason within the Change in Control Period. The provisions of this Section 6 shall apply in lieu of, and expressly supersede, the provisions of Section 5 if (i) the Executive's employment is terminated either (a) by the Company without Cause as provided in Section 3(d), or (b) by the Executive for Good Reason as provided in Section 3(e), and (ii) the Date of Termination is during the Change in Control Period. The "***Change in Control Period***" shall begin on the earlier of (a) the signing of a P&S Agreement and (b) the date that is 3 months prior to the closing of a Change in Control, and shall end on the date that is twelve (12) months after the occurrence of the first event constituting a Change in Control. These provisions shall terminate and be of no further force or effect after the Change in Control Period. In no event will the Executive be entitled to severance benefits under both Section 5 and Section 6 of this Agreement. If the Company has commenced providing severance pay and benefits to the Executive under Section 5 prior to the date that the Executive becomes eligible to receive severance pay and benefits under this Section 6, the severance pay and benefits previously provided to the Executive under Section 5 shall reduce the severance pay and benefits to be provided under this Section 6.

If the Executive's employment is terminated by the Company without Cause as provided in Section 3(d) or the Executive terminates employment for Good Reason as provided in Section 3(e) and in each case the Date of Termination occurs during the Change in Control Period, then, in addition to the Accrued Obligations, and subject to the signing of the Separation Agreement by the Executive and the Separation Agreement becoming fully effective, all within the time

frame set forth in the Separation Agreement but in no event more than sixty (60) days after the Date of Termination:

(a) Cash Severance. The Company shall pay the Executive a lump sum in cash in an amount equal to the sum of (A) twelve (12) months' of the Executive's then-current Base Salary (or the Executive's Base Salary in effect immediately prior to the Change in Control, if higher), and (B) the Executive's Target Bonus for the then-current year (or the Executive's Target Bonus in effect immediately prior to the Change in Control, if higher), plus, if applicable, any Earned Bonus (the "***Change in Control Payment***").

(b) COBRA Premiums. Subject to the Executive's copayment of premium amounts at the applicable active employees' rate and the Executive's proper election to receive benefits under COBRA, the Company shall pay to the group health plan provider or the COBRA provider a monthly payment equal to the monthly employer contribution that the Company would have made to provide health insurance to the Executive if the Executive had remained employed by the Company until the earliest of (A) the twelve (12) month anniversary of the Date of Termination; (B) the date that the Executive becomes eligible for group medical plan benefits under any other employer's group medical plan; or (C) the cessation of the Executive's health continuation rights under COBRA; provided, however, that if the Company determines that it cannot pay such amounts to the group health plan provider or the COBRA provider (if applicable) without potentially violating applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then the Company shall convert such payments to payroll payments directly to the Executive for the time period specified above. Such payments to the Executive shall be subject to tax-related deductions and withholdings and paid on the Company's regular payroll dates.

(c) Accelerated Vesting of Equity Awards. Notwithstanding anything to the contrary in any Equity Award, the Time-Based Equity Awards shall immediately accelerate and become fully vested and exercisable or nonforfeitable as if the Executive had remained employed with the Company as of the later of (i) the Date of Termination (or, if later, the Change in Control) or (ii) the effective date of the Separation Agreement (the "***Accelerated Vesting Date***"), provided that in order to effectuate the accelerated vesting contemplated by this subsection, the unvested portion of such Equity Awards that would otherwise terminate or be forfeited on the Date of Termination will be delayed until the earlier of (A) the effective date of the Separation Agreement (at which time acceleration will occur), or (B) the date that the Separation Agreement can no longer become fully effective (at which time the unvested portion of the Executive's Time-Based Equity Awards will terminate or be forfeited). Notwithstanding the foregoing, no additional time-based vesting of the Time-Based Equity Awards shall occur during the period between the Date of Termination and the Accelerated Vesting Date except as specifically provided in this Section 6(c).

(d) Change in Control Payment Timing. The amounts payable under this Section 6, to the extent taxable, shall be paid or commence to be paid within sixty (60) days after the Date of Termination or, if later, the Change in Control; provided, however, that if the 60-day period begins in one calendar year and ends in a second calendar year, such payments to the extent they qualify as "non-qualified deferred compensation" within the meaning of Section

409A of the Code, shall be paid or commence to be paid in the second calendar year by the last day of such 60-day period.

7. 280G Limitation.

(a) Anything in this Agreement to the contrary notwithstanding, in the event that the amount of any compensation, payment or distribution by the Company to or for the benefit of the Executive, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, calculated in a manner consistent with Section 280G of the Code, and the applicable regulations thereunder (the "***Aggregate Payments***"), would be subject to the excise tax imposed by Section 4999 of the Code, then the Aggregate Payments shall be reduced (but not below zero) so that the sum of all of the Aggregate Payments shall be $1.00 less than the amount at which the Executive becomes subject to the excise tax imposed by Section 4999 of the Code; provided that such reduction shall only occur if it would result in the Executive receiving a higher After Tax Amount (as defined below) than the Executive would receive if the Aggregate Payments were not subject to such reduction. In such event, the Aggregate Payments shall be reduced in the following order, in each case, in reverse chronological order beginning with the Aggregate Payments that are to be paid the furthest in time from consummation of the transaction that is subject to Section 280G of the Code: (1) cash payments not subject to Section 409A of the Code; (2) cash payments subject to Section 409A of the Code; (3) equity-based payments and acceleration; and (4) non-cash forms of benefits; provided that in the case of all the foregoing Aggregate Payments all amounts or payments that are not subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c) shall be reduced before any amounts that are subject to calculation under Treas. Reg. §1.280G-1, Q&A-24(b) or (c).

(b) For purposes of this Section 7, the "***After Tax Amount***" means the amount of the Aggregate Payments less all federal, state, and local income, excise and employment taxes imposed on the Executive as a result of the Executive's receipt of the Aggregate Payments. For purposes of determining the After Tax Amount, the Executive shall be deemed to pay federal income taxes at the highest marginal rate of federal income taxation applicable to individuals for the calendar year in which the determination is to be made, and state and local income taxes at the highest marginal rates of individual taxation in each applicable state and locality, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes.

(c) For purposes of determining whether and the extent to which the Aggregate Payments will be subject to the excise tax, (i) no portion of the Aggregate Payments the receipt or enjoyment of which Executive shall have waived at such time and in such manner as not to constitute a "payment" within the meaning of Section 280G(b) of the Code shall be taken into account, (ii) no portion of the Aggregate Payments shall be taken into account which, in the written opinion of independent auditors or advisors of nationally recognized standing ("***Independent Advisors***") selected by the Company prior to a Change in Control, does not constitute a "parachute payment" within the meaning of Section 280G(b)(2) of the Code (including by reason of Section 280G(b)(4)(A) of the Code) and, in calculating the excise tax, no portion of such Aggregate Payments shall be taken into account which, in the opinion of Independent Advisors, constitutes reasonable compensation for services actually rendered,

within the meaning of Section 280G(b)(4)(B) of the Code, in excess of the "base amount" (as defined in Section 280G(b)(3) of the Code) allocable to such reasonable compensation, and (iii) the value of any non-cash benefit or any deferred payment or benefit included in the Aggregate Payments shall be determined by the Independent Advisors in accordance with the principles of Sections 280G(d)(3) and (4) of the Code. The Independent Advisors shall provide detailed supporting calculations both to the Company and the Executive within fifteen (15) business days of the Date of Termination, if applicable, or at such earlier time as is reasonably requested by the Company or the Executive. Any determination by the Independent Advisors shall be binding upon the Company and the Executive.

8. Section 409A.

(a) Anything in this Agreement to the contrary notwithstanding, if at the time of the Executive's separation from service within the meaning of Section 409A of the Code, the Company determines that the Executive is a "specified employee" within the meaning of Section 409A(a)(2)(B)(i) of the Code, then to the extent any payment or benefit that the Executive becomes entitled to under this Agreement or otherwise on account of the Executive's separation from service would be considered deferred compensation otherwise subject to the 20% additional tax imposed pursuant to Section 409A(a) of the Code as a result of the application of Section 409A(a)(2)(B)(i) of the Code, such payment shall not be payable and such benefit shall not be provided until the date that is the earlier of (A) six (6) months and one day after the Executive's separation from service, or (B) the Executive's death. If any such delayed cash payment is otherwise payable on an installment basis, the first payment shall include a catch-up payment covering amounts that would otherwise have been paid during the 6-month period but for the application of this provision, and the balance of the installments shall be payable in accordance with their original schedule.

(b) All in-kind benefits provided and expenses eligible for reimbursement under this Agreement shall be provided by the Company or incurred by the Executive during the time periods set forth in this Agreement. All reimbursements shall be paid as soon as administratively practicable, but in no event shall any reimbursement be paid after the last day of the taxable year following the taxable year in which the expense was incurred. The amount of in-kind benefits provided or reimbursable expenses incurred in one taxable year shall not affect the in-kind benefits to be provided or the expenses eligible for reimbursement in any other taxable year (except for any lifetime or other aggregate limitation applicable to medical expenses). Such right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit.

(c) To the extent that any payment or benefit described in this Agreement constitutes "non-qualified deferred compensation" under Section 409A of the Code, and to the extent that such payment or benefit is payable upon the Executive's termination of employment, then such payments or benefits shall be payable only upon the Executive's "separation from service." The determination of whether and when a separation from service has occurred shall be made in accordance with the presumptions set forth in Treasury Regulation Section 1.409A-1(h).

(d) The parties intend that this Agreement will be administered in a manner not intended to violate Section 409A of the Code. To the extent that any provision of this

Agreement is ambiguous as to its compliance with Section 409A of the Code, the provision shall be read in such a manner so that all payments hereunder comply with Section 409A of the Code. Each payment pursuant to this Agreement is intended to constitute a separate payment for purposes of Treasury Regulation Section 1.409A-2(b)(2). Any such payment that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral (each as described in Treasury regulations issued under Section 409A) shall be excluded from Section 409A to the greatest extent possible. The parties agree that this Agreement may be amended, as reasonably requested by either party, and as may be necessary to fully comply with Section 409A of the Code and all related rules and regulations in order to preserve the payments and benefits provided hereunder without additional cost to either party.

(e) The Company makes no representation or warranty and shall have no liability to the Executive or any other person if any provisions of this Agreement are determined to constitute deferred compensation subject to Section 409A of the Code but do not satisfy an exemption from, or the conditions of, such Section.

9. Continuing Obligations.

(a) Restrictive Covenants Agreement. As a condition of entering into this Agreement, Executive agrees to the terms of the Employee Proprietary Information and Inventions Assignment Agreement, dated September 22, 2021, between the Company and the Executive (the "***Restrictive Covenants Agreement***"). For purposes of this Agreement, the obligations in this Section 9 and those that arise in the Restrictive Covenants Agreement and any other agreement relating to confidentiality, assignment of inventions, or other restrictive covenants that may later be agreed to by the Executive shall collectively be referred to as the "***Continuing Obligations***."

(b) Third-Party Agreements and Rights. The Executive hereby confirms that the Executive is not bound by the terms of any agreement with any previous employer or other party which restricts in any way the Executive's use or disclosure of information, other than confidentiality restrictions (if any), or the Executive's engagement in any business. The Executive represents to the Company that the Executive's execution of this Agreement, the Executive's employment with the Company and the performance of the Executive's proposed duties for the Company will not violate any obligations the Executive may have to any such previous employer or other party. In the Executive's work for the Company, the Executive will not disclose or make use of any information in violation of any agreements with or rights of any such previous employer or other party, and the Executive will not bring to the premises of the Company any copies or other tangible embodiments of non-public information belonging to or obtained from any such previous employment or other party.

(c) Litigation and Regulatory Cooperation. During and after the Executive's employment, the Executive shall cooperate fully with the Company in (i) the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while the Executive was employed by the Company, and (ii) the investigation, whether internal or external, of any matters about which the Company believes the Executive may have knowledge

or information. The Executive's full cooperation in connection with such claims, actions or investigations shall include, but not be limited to, being available to meet with counsel upon reasonable notice to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company at mutually convenient times. During and after the Executive's employment, the Executive also shall cooperate fully with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while the Executive was employed by the Company. The Company shall reimburse the Executive for any reasonable out-of-pocket expenses incurred in connection with the Executive's performance of obligations pursuant to this Section 9(c), which shall be in addition to its obligations to provide indemnification to the Executive.

(d) Relief. The Executive agrees that it would be difficult to measure any damages caused to the Company which might result from any breach by the Executive of the Continuing Obligations, and that in any event monetary damages would be an inadequate remedy for any such breach. Accordingly**,** the Executive agrees that if the Executive breaches, or proposes to breach, any portion of the Continuing Obligations, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company.

10. Consent to Jurisdiction. The parties hereby consent to the jurisdiction of the state and federal courts of New Jersey. Accordingly, with respect to any such court action, the Executive (a) submits to the exclusive personal jurisdiction of such courts; (b) consents to service of process; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process.

11. Integration. This Agreement constitutes the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior agreements between the parties concerning such subject matter**,** including the Prior Agreement, provided that the Restrictive Covenants Agreement and the agreements governing any Equity Awards remain in full force and effect.

12. Withholding; Tax Effect. All payments made by the Company to the Executive under this Agreement shall be net of any tax or other amounts required to be withheld by the Company under applicable law. Nothing in this Agreement shall be construed to require the Company to make any payments to compensate the Executive for any adverse tax effect associated with any payments or benefits or for any deduction or withholding from any payment or benefit.

13. Successors and Assigns. This Agreement will be binding upon and inure to the benefit of (a) the heirs, executors, and legal representatives of Executive upon Executive's death as well as any beneficiaries duly designated by Executive prior to death in accordance with the terms hereof, and (b) any successor of the Company. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation, or other business entity which at any time, whether by purchase, merger, or otherwise, directly or indirectly acquires all or

substantially all of the assets or business of the Company. The Company shall require its respective successors to expressly assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it if no such succession had taken place. Notwithstanding the foregoing, the Company shall remain, with such successor, jointly and severally liable for all of their obligations hereunder. Except as herein provided, this Agreement may not otherwise be assigned by the Company and any attempted assignment in contravention hereof will be null and void. In the event of the Executive's death after the Executive's termination of employment but prior to the completion by the Company of all payments due to the Executive under this Agreement, the Company shall continue such payments to the Executive's beneficiary designated in writing to the Company prior to the Executive's death (or to the Executive's estate, if the Executive fails to make such designation). The Executive may designate one or more persons or entities as the primary or contingent beneficiaries of any amounts to be received under this Agreement. Such designation must be in the form of a signed writing reasonably acceptable to the Board or the Board's designee. Executive may make or change such designation at any time. Except as approved by the Board or the Board's designee, none of the rights of the Executive to receive any form of compensation payable pursuant to this Agreement may be assigned or transferred except by will or the laws of descent and distribution. Any other attempted assignment, transfer, conveyance, or other disposition of Executive's right to compensation or other benefits will be null and void.

14. Enforceability. If any portion or provision of this Agreement (including, without limitation, any portion or provision of any section of this Agreement) shall to any extent be declared illegal or unenforceable by a court of competent jurisdiction, then the remainder of this Agreement, or the application of such portion or provision in circumstances other than those as to which it is so declared illegal or unenforceable, shall not be affected thereby, and each portion and provision of this Agreement shall be valid and enforceable to the fullest extent permitted by law.

15. Survival. The provisions of this Agreement shall survive the termination of this Agreement and/or the termination of the Executive's employment to the extent necessary to effectuate the terms contained herein, including but not limited to the Company's obligation to make severance payments or provide indemnification and the Executive's obligations to comply with the Continuing Obligations.

16. Waiver. No waiver of any provision hereof shall be effective unless made in writing and signed by the waiving party. The failure of any party to require the performance of any term or obligation of this Agreement, or the waiver by any party of any breach of this Agreement, shall not prevent any subsequent enforcement of such term or obligation or be deemed a waiver of any subsequent breach.

17. Notices. Any notices, requests, demands and other communications provided for by this Agreement shall be sufficient if in writing and (i) delivered in person, (ii) sent by a nationally recognized overnight courier service or by registered or certified mail, postage prepaid, return receipt requested, to the Executive at the last address the Executive has filed in writing with the Company or, in the case of the Company, at its main offices, attention of the Board or (iii) sent via email to the Executive at the Executive's Company email address or, in the case of the Company, to the CEO's Company email address.

18. Amendment. This Agreement may be amended or modified only by a written instrument signed by the Executive and by a duly authorized representative of the Company.

19. Indemnification. The Company will (i) indemnify the Executive with respect to claims arising out of any action taken or not taken in Executive's capacity as an officer or employee of the Company or its subsidiaries; provided, that the Executive acted in good faith and in a manner that Executive reasonably believed to be in or not opposed to the best interests of the Company and, with respect to any criminal action or proceeding, had no reasonable cause to believe that Executive's conduct was unlawful, (ii) advance to the Executive all reasonable and documented out of pocket costs and expenses incurred by the Executive in connection with the foregoing clause (i), including but not limited to attorneys' fees, and (iii) provide for the Executive to be covered by D&O insurance, with respect to clauses (i) and (ii), on the same terms as are made available to the CEO and/or members of the Board, as applicable; provided that, this Agreement constitutes an undertaking that amounts advanced under clause (ii) shall be promptly repaid to the Company by the Executive if it shall ultimately be determined that the Executive is not entitled to be indemnified by the Company pursuant to this Section 19. Nothing herein shall limit any right that the Executive may have in respect of indemnification, advancement or liability insurance coverage under any other policy, plan, contract or arrangement of the Company or its subsidiaries or under applicable law with respect to his or her services as an officer or employee for the Company or its subsidiaries, and the Company shall not change any right to such indemnification or advancement with respect to the Executive after his or her termination of employment.

20. No Mitigation; Offset. In the event of any termination of employment and service hereunder, the Executive shall be under no obligation to seek other employment, and there shall be no offset against any amounts due Executive under this Agreement on account of any remuneration attributable to any subsequent employment that Executive may obtain. The preceding sentence shall not limit the Company's right to enforce the termination provisions set forth in Section 4 above or the repayment or recoupment provisions in Section 22(d) and Section 23 below.

21. Effect on Other Plans and Agreements. An election by the Executive to resign for Good Reason under the provisions of this Agreement shall not be deemed a voluntary termination of employment by the Executive for the purpose of interpreting the provisions of any of the Company's benefit plans, programs or policies. Nothing in this Agreement shall be construed to limit the rights of the Executive under the Company's benefit plans, programs or policies except to the extent specifically provided in Section 7 hereof, and except that the Executive shall have no rights to continue any severance benefits under any Company severance pay plan, offer letter or otherwise. Except for the Restrictive Covenants Agreement, in the event that the Executive is party to an agreement with the Company providing for payments or benefits under such plan or agreement and under this Agreement, the terms of this Agreement shall govern and the Executive may receive payment under this Agreement only and not both. Further, Section 5 and Section 6 of this Agreement are mutually exclusive and in no event shall the Executive be entitled to cash severance payments or benefits pursuant to both Section 5 and Section 6 of this Agreement.

22. Governing Law; Venue and Enforcement.

(a) This Agreement will be governed by and construed in accordance with applicable federal laws and, to the extent not inconsistent therewith or preempted thereby, with the laws of New Jersey, including any applicable statutes of limitation, without regard to any otherwise applicable principles of conflicts of laws or choice of law rules (whether of New Jersey or any other jurisdiction) that would result in the application of the substantive or procedural rules or law of any other jurisdiction.

(b) Each party agrees that any controversy or claim arising out of or relating to this Agreement or the alleged breach hereof shall be instituted in the United States District Court for the District of New Jersey, or if that court does not have or will not accept jurisdiction, in any court of general jurisdiction in the District of New Jersey, and Executive and the Company hereby consent to the personal and exclusive jurisdiction of such court(s) and hereby waive any objection(s) that any such party may have to personal jurisdiction, the laying of venue of any such proceedings and any claim or defense of inconvenient forum.

(c) Any award shall be payable to Executive no later than the end of Executive's first taxable year in which the Company either concede the amount (or portion of the amount) payable or are required to make payment pursuant to a judgment by a court, and shall include interest on any amounts due and payable to Executive from the date due to the date of payment, calculated at one hundred and ten percent (110%) of the base lending in effect at Citibank, N.A. (or any successor thereto) on the first of each month.

(d) If it is necessary or desirable for Executive to retain legal counsel or incur other costs and expenses in connection with the enforcement of any or all of Executive's rights under this Agreement, the Company shall, within thirty (30) days after receipt of an invoice certifying payment by Executive of such attorney fees, or payment of such other costs and expenses, reimburse Executive's reasonable attorneys' fees and costs and such other expenses, including expenses of any expert witnesses, in connection with the enforcement of said rights in an amount not to exceed $100,000; provided, that to the extent (and only to the extent) such expenses are subject to Section 409A, in no event shall any payment of Executive's fees, costs, and expenses be made after the last day of Executive's taxable year following the taxable year in which the expense was incurred; provided, further, that Executive shall repay any such advance of fees, costs, and expenses (and no additional advances or reimbursements shall be made) (i) if there is a specific judicial finding that Executive's request to litigate was frivolous, unreasonable or without foundation; (ii) if it has been finally determined that Executive's termination of employment for Cause was proper; or (iii) if the Board determines in good faith that as of the date of Executive's termination of employment and service, grounds for an involuntary termination for Cause had existed.

23. Recoupment. Executive shall be required to repay incentive pay to the Company as described in this Section 23, and the Company may offset payments otherwise due and payable under this Agreement by the amounts required to be repaid under this Section 23. Repayment of incentive pay shall be required if, and to the extent that, the Compensation Committee determines, in its sole discretion, that repayment is due on account of a restatement of the Company's financial statements or otherwise pursuant to any clawback or compensation recoupment policy as may be in effect or amended from time to time) (the "***Recoupment Policy***"). Where the result of a performance measure was a factor in determining the

compensation awarded or paid, but (i) the subsequently-restated performance measure was not the only factor used to determine the compensation awarded or paid, or (ii) the incentive-based compensation is not awarded or paid on a formulaic basis, the Committee will determine in its discretion the amount, if any, by which the payment or award should be reduced. If the Committee seeks to recover payment of incentive pay as a result of a restatement of the Company's financial statements or otherwise under the Recoupment Policy, Executive shall pay to the Company, as applicable, (A) all or a portion (as determined by the Committee in its sole discretion) of the amount by which the payment received by Executive exceeds the amount that would have been paid to Executive based on the restated financial statements, or (B) the amount (as determined by the Committee in its sole discretion) to be repaid pursuant to the Recoupment Policy. Nothing in this Section 23 shall preclude the Company (or any other person) from taking any other action.

24. Counterparts. This Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

IN WITNESS WHEREOF, the parties have executed this Agreement effective on the Effective Date.

ADAGIO THERAPEUTICS, INC.

By: /s/ Tillman Gerngross
Its: CEO

EXECUTIVE

/s/ Jill Andersen
Jill Andersen

Appendix A

Outside Activities

Director, Girl Scouts of Northern New Jersey, Board of Directors (2020-Present)

Appendix B

FORM SEPARATION AGREEMENT

[Date]

[Name]
[Address]

Re: Separation Agreement

Dear [Name]:

This letter sets forth the substance of the separation agreement (the "Agreement") which Adagio Therapeutics, Inc. (the "Company") is offering to you to aid in your employment transition.

1.Separation. Your last day of work with the Company and your employment termination date will be [Date] (the "Separation Date").

2.Accrued Salary. On the Separation Date, the Company will pay you all accrued salary earned through the Separation Date, subject to standard payroll deductions and withholdings. You will receive these payments regardless of whether or not you sign this Agreement.

3.Severance Benefits. If you execute and do not revoke this Agreement, the Company will provide you with the following Severance Benefits pursuant to the terms of your [month, date, year] Employment Agreement.

The Company is offering severance to you in reliance on Treasury Regulation Section 1.409A-1(b)(9) and the short term deferral exemption in Treasury Regulation Section 1.409A-1(b)(4). Any payments made in reliance on Treasury Regulation Section 1.409A-1(b)(4) will be made not later than March 15, 20__. For purposes of Code Section 409A, your right to receive any installment payments under this Agreement (whether severance payments, reimbursements or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment.

4.Benefit Plans.

If you are currently participating in the Company's group health insurance plans, your participation as an employee will end on [the Separation Date] *or* [the last day of the month in which separation occurs]. Thereafter, to the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, you will be eligible to continue your group health insurance benefits at your own expense. Later, you may be able to convert to an individual policy through the provider of the Company's health insurance, if you wish.

Deductions for the 401(k) Plan will end with your last regular paycheck. You will receive information by mail concerning 401(k) plan rollover procedures should you be a participant in this program.

You may be eligible for unemployment insurance benefits after the Separation Date. The Massachusetts Department of Unemployment Assistance, not the Company, will determine your eligibility for such benefits.

5.Stock Options. You were granted an option to purchase _____ shares of the Company's common stock, pursuant to the Company's [correct name of Stock or incentive plan] (the "Plan"). Under the terms of the Plan and your stock option grant, vesting will cease as of the Separation Date.

6.Other Compensation or Benefits. You acknowledge that, except as expressly provided in this Agreement, you will not receive any additional compensation, severance or benefits after the Separation Date.

7.Expense Reimbursements. You agree that, within ten (10) days of the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement. The Company will reimburse you for reasonable business expenses pursuant to its regular business practice.

8.Return of Company Property. By the Separation Date, you agree to return to the Company all Company documents (and all copies thereof) and other Company property that you have had in your possession at any time, including, but not limited to, Company files, notes, drawings, records, business plans and forecasts, financial information, specifications, computer-recorded information, tangible property (including, but not limited to, computers), credit cards, entry cards, identification badges and keys; and, any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). Please coordinate return of Company property with [name/title]. **Receipt of the severance benefits described in Section 3 of this Agreement is expressly conditioned upon return of all Company Property.**

9.Confidential Information and Post-Termination Obligations. Both during and after your employment you acknowledge your continuing obligations under your Employee Proprietary Information and Inventions Assignment Agreement ("Restrictive Covenants Agreement") not to use or disclose any confidential or proprietary information of the Company and to refrain from certain solicitation activities. A copy of your Restrictive Covenants Agreement is attached hereto. If you have any doubts as to the scope of the restrictions in your agreement, you should contact [name/title] immediately to assess your compliance. As you know, the Company will enforce its contract rights. Please familiarize yourself with the enclosed agreement which you signed. Confidential information that is also a "trade secret," as defined by law, may be disclosed (A) if it is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, in the event that you file a lawsuit for

retaliation by the Company for reporting a suspected violation of law, you may disclose the trade secret to your attorney and use the trade secret information in the court proceeding, if you: (A) file any document containing the trade secret under seal; and (B) do not disclose the trade secret, except pursuant to court order.

10.Non-Compete. In exchange for the payments and other consideration under this Agreement, to which you would not otherwise be entitled, you agree that during the one year period after the Separation Date, you will not, whether paid or not: (i) serve as a partner, principal, licensor, licensee, employee, consultant, officer, director, manager, agent, affiliate, representative, advisor, promoter, associate, investor, or otherwise for, (ii) directly or indirectly, own, purchase, organize or take preparatory steps for the organization of, or (iii) build, design, finance, acquire, lease, operate, manage, control, invest in, work or consult for or otherwise join, participate in or affiliate yourself with, any business whose business, products or operations are in any respect involved in Conflicting Services (defined below) anywhere in the Restricted Territory (defined below). Should you obtain other employment within 12 months immediately following the Separation Date, you agree to provide written notification to the Company as to the name and address of your new employer, the position that you expect to hold, and a general description of your duties and responsibilities, at least three business days prior to starting such employment.

a) The parties agree that for purposes of this Agreement, "Conflicting Services" means any business in which the Company is engaged, or in which the Company has plans to be engaged, or any service that the Company provides or has plans to provide.

b) The parties further agree that for purposes of this Agreement, "Restricted Territory" means the geographic areas in which you provided services for the Company or had a material presence or influence, during any time within the last two years prior to the Separation Date.

11.Confidentiality. The provisions of this Agreement will be held in strictest confidence by you and will not be publicized or disclosed in any manner whatsoever; *provided, however,* that: (a) you may disclose this Agreement to your immediate family; (b) you may disclose this Agreement in confidence to your attorney, accountant, auditor, tax preparer, and financial advisor; and (c) you may disclose this Agreement insofar as such disclosure may be required by law. Notwithstanding the foregoing, nothing in this Agreement shall limit your right to voluntarily communicate with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of your employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

12.Non-Disparagement. You agree not to disparage the Company, and the Company's attorneys, directors, managers, partners, employees, agents and affiliates, in any manner likely to be harmful to them or their business, business reputation or personal reputation; provided that you may respond accurately and fully to any question, inquiry or request for information when required by legal process. You further agree that, by no later than the Effective Date, you shall delete or otherwise remove any and all disparaging public comments or statements that you made prior to the Effective Date about or relating to the Company, including, but not limited to, comments in online forums or on websites (including, but not limited to, Facebook, Glassdoor, Yelp, and

LinkedIn). Notwithstanding the foregoing, nothing in this Agreement shall limit your right to voluntarily communicate with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of your employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act.

13.Cooperation after Termination. You agree to cooperate fully with the Company in all matters relating to the transition of your work and responsibilities on behalf of the Company, including, but not limited to, any present, prior or subsequent relationships and the orderly transfer of any such work and institutional knowledge to such other persons as may be designated by the Company, by making yourself reasonably available during regular business hours.

14.Release. In exchange for the payments and other consideration under this Agreement, to which you would not otherwise be entitled, and except as otherwise set forth in this Agreement, you, on behalf of yourself and, to the extent permitted by law, on behalf of your spouse, heirs, executors, administrators, assigns, insurers, attorneys and other persons or entities, acting or purporting to act on your behalf (collectively, the "Employee Parties"), hereby generally and completely release, acquit and forever discharge the Company, its parents and subsidiaries, and its and their officers, directors, managers, partners, agents, representatives, employees, attorneys, shareholders, predecessors, successors, assigns, insurers and affiliates (the "Company Parties") of and from any and all claims, liabilities, demands, contentions, actions, causes of action, suits, costs, expenses, attorneys' fees, damages, indemnities, debts, judgments, levies, executions and obligations of every kind and nature, in law, equity, or otherwise, both known and unknown, suspected and unsuspected, disclosed and undisclosed, arising out of or in any way related to agreements, events, acts or conduct at any time prior to and including the execution date of this Agreement, including but not limited to: all such claims and demands directly or indirectly arising out of or in any way connected with your employment with the Company or the termination of that employment; claims or demands related to salary, bonuses, commissions, stock, stock options, or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, severance pay, or any other form of compensation; claims pursuant to any federal, state or local law, statute, or cause of action; tort law; or contract law (individually a "Claim" and collectively "Claims"). The Claims you are releasing and waiving in this Agreement include, but are not limited to, any and all Claims that any of the Company Parties:

- has violated its personnel policies, handbooks, contracts of employment, or covenants of good faith and fair dealing;

- has discriminated against you on the basis of age, race, color, sex (including sexual harassment), national origin, ancestry, disability, religion, sexual orientation, marital status, parental status, source of income, entitlement to benefits, any union activities or other protected category in violation of any local, state or federal law, constitution, ordinance, or regulation, including but not limited to: Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1866 (42 U.S.C. 1981), the Civil Rights Act of 1991, the Genetic Information Nondiscrimination Act, Executive Order 11246, which prohibit discrimination based on race, color, national origin, religion, or sex; the Americans with

Disabilities Act and Sections 503 and 504 of the Rehabilitation Act of 1973, which prohibit discrimination against the disabled, the Age Discrimination in Employment Act (ADEA), which prohibits discrimination based on age, the Older Workers Benefit Protection Act, the National Labor Relations Act, the Lily Ledbetter Fair Pay Act, the anti-retaliation provisions of the Sarbanes-Oxley Act, or any other federal or state law regarding whistleblower retaliation; the Massachusetts Fair Employment Practices Act (M.G.L. c. 151B), the Massachusetts Equal Rights Act, the Massachusetts Equal Pay Act, the Massachusetts Privacy Statute, the Massachusetts Sick Leave Law, the Massachusetts Civil Rights Act, all as amended, and any and all other federal, state or local laws, rules, regulations, constitutions, ordinances or public policies, whether known or unknown, prohibiting employment discrimination;

- has violated any employment statutes, such as the WARN Act, which requires that advance notice be given of certain workforce reductions; the Employee Retirement Income Security Act of 1974 (ERISA) which, among other things, protects employee benefits; the Fair Labor Standards Act of 1938, which regulates wage and hour matters; the National Labor Relations Act, which protects forms of concerted activity; the Family and Medical Leave Act of 1993, which requires employers to provide leaves of absence under certain circumstances; the Fair Credit Reporting Act, the Employee Polygraph Protection Act, the Massachusetts Payment of Wages Act (M.G.L. c. 149 sections 148 and 150), the Massachusetts Overtime regulations (M.G.L. c. 151 sections 1A and 1B), the Massachusetts Meal Break regulations (M.G.L. c. 149 sections 100 and 101), all as amended, and any and all other federal, state or local laws, rules, regulations, constitutions, ordinances or public policies, whether known or unknown relating to employment laws, such as veterans' reemployment rights laws;

- has violated any other laws, such as federal, state, or local laws providing workers' compensation benefits, restricting an employer's right to terminate employees, or otherwise regulating employment; any federal, state or local law enforcing express or implied employment contracts or requiring an employer to deal with employees fairly or in good faith; any other federal, state or local laws providing recourse for alleged wrongful discharge, retaliatory discharge, negligent hiring, retention, or supervision, physical or personal injury, emotional distress, assault, battery, false imprisonment, fraud, negligent misrepresentation, defamation, intentional or negligent infliction of emotional distress and/or mental anguish, intentional interference with contract, negligence, detrimental reliance, loss of consortium to you or any member of your family, whistleblowing, and similar or related claims.

Notwithstanding the foregoing, other than events expressly contemplated by this Agreement you do not waive or release rights or Claims that may arise from events that occur after the date this waiver is executed or your right to enforce this Agreement. Also excluded from this Agreement are any Claims which cannot be waived by law, including, without limitation, any rights you may have under applicable workers' compensation laws and your right, if applicable, to file or participate in an investigative proceeding of any federal, state or local governmental agency.

Nothing in this Agreement shall prevent you from filing, cooperating with, or participating in any proceeding or investigation before the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal government agency, or similar state or local agency ("Government Agencies"), or exercising any rights pursuant to Section 7 of the National Labor Relations Act. You further understand this Agreement does not limit your ability to voluntarily communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, you are otherwise waiving, to the fullest extent permitted by law, any and all rights you may have to individual relief based on any Claims that you have released and any rights you have waived by signing this Agreement. If any Claim is not subject to release, to the extent permitted by law, you waive any right or ability to be a class or collective action representative or to otherwise participate in any putative or certified class, collective or multi-party action or proceeding based on such a Claim in which any of the Company Parties is a party. This Agreement does not abrogate your existing rights under any Company benefit plan or any plan or agreement related to equity ownership in the Company; however, it does waive, release and forever discharge Claims existing as of the date you execute this Agreement pursuant to any such plan or agreement.

15.Your Acknowledgments and Affirmations/ Effective Date of Agreement. You acknowledge that you are knowingly and voluntarily waiving and releasing any and all rights you may have under the ADEA, as amended. You also acknowledge and agree that (i) the consideration given to you in exchange for the waiver and release in this Agreement is in addition to anything of value to which you were already entitled, and (ii) that you have been paid for all time worked, have received all the leave, leaves of absence and leave benefits and protections for which you are eligible, and have not suffered any on-the-job injury for which you have not already filed a Claim. You affirm that all of the decisions of the Company Parties regarding your pay and benefits through the date of your execution of this Agreement were not discriminatory based on age, disability, race, color, sex, religion, national origin or any other classification protected by law. You affirm that you have not filed or caused to be filed, and are not presently a party to, a Claim against any of the Company Parties. You further affirm that you have no known workplace injuries or occupational diseases. You acknowledge and affirm that you have not been retaliated against for reporting any allegation of corporate fraud or other wrongdoing by any of the Company Parties, or for exercising any rights protected by law, including any rights protected by the Fair Labor Standards Act, the Family Medical Leave Act or any related statute or local leave or disability accommodation laws, or any applicable state workers' compensation law. You further acknowledge and affirm that you have been advised by this writing that: (a) your waiver and release do not apply to any rights or Claims that may arise after the execution date of this Agreement; (b) you have been advised hereby that you have the right to consult with an attorney prior to executing this Agreement; (c) you have been given twenty-one (21) days to consider this Agreement (although you may choose to voluntarily execute this Agreement earlier and if you do you will sign the Consideration Period waiver below); (d) you have seven (7) business days following your execution of this Agreement to revoke this Agreement; and (e) this Agreement

shall not be effective until the date upon which the revocation period has expired unexercised (the "Effective Date"), which shall be the eighth business day after this Agreement is executed by you.

16.No Admission. This Agreement does not constitute an admission by the Company of any wrongful action or violation of any federal, state, or local statute, or common law rights, including those relating to the provisions of any law or statute concerning employment actions, or of any other possible or claimed violation of law or rights.

17.Breach. You agree that upon any breach of this Agreement you will forfeit all amounts paid or owing to you under this Agreement. Further, you acknowledge that it may be impossible to assess the damages caused by your violation of the terms of Sections 8, 9, 10 and 11 of this Agreement and further agree that any threatened or actual violation or breach of those Sections of this Agreement will constitute immediate and irreparable injury to the Company. You therefore agree that any such breach of this Agreement is a material breach of this Agreement, and, in addition to any and all other damages and remedies available to the Company upon your breach of this Agreement, the Company shall be entitled to an injunction to prevent you from violating or breaching this Agreement. You agree that if the Company is successful in whole or part in any legal or equitable action against you under this Agreement, you agree to pay all of the costs, including reasonable attorneys' fees, incurred by the Company in enforcing the terms of this Agreement.

18.Miscellaneous. This Agreement, including any exhibits, constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the provision in question will be modified by the court so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the Commonwealth of Massachusetts as applied to contracts made and to be performed entirely within Massachusetts.

19. To ensure the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims (including, but not limited to, the Massachusetts Antidiscrimination Act, Mass. Gen. Laws ch.151B and the Massachusetts Wage Act, Mass. Gen. Laws ch. 149), arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding.** You

will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this Agreement is intended to prevent either you or the Company from obtaining injunctive relief in court to prevent irreparable harm pending the conclusion of any such arbitration.

If this Agreement is acceptable to you, please sign below and return the original to me on or after your Separation Date, but no later than the date that is twenty-one (21) days after you receive this Agreement. This offer will expire if we have not received your executed copy by that date.

I wish you good luck in your future endeavors.

Sincerely,

Adagio Therapeutics, Inc.

By: _____
[Name]
[Title]

AGREED TO AND ACCEPTED:

_____
Jill Andersen

CONSIDERATION PERIOD

I, _____, understand that I have the right to take at least 21 days to consider whether to sign this Agreement, which I received on _____ __, 20__. If I elect to sign this Agreement before 21 days have passed, I understand I am to sign and date below this paragraph to confirm that I knowingly and voluntarily agree to waive the 21-day consideration period.

AGREED:

____
Signature

_____
Date

FIRST AMENDMENT TO THE AMENDED AND RESTATED EMPLOYMENT AGREEMENT OF JANE HENDERSON

This First Amendment to the Amended and Restated Employment Agreement of Jane Henderson (the "***Amendment***") is entered into this 18th day of March 2022 (the "***Amendment Effective Date***"), by and between Jane Henderson (the "***Executive***") and **Adagio Therapeutics, Inc.** (the "***Company***").

Recitals

WHEREAS, the Company and the Executive have entered into that certain Amended and Restated Employment Agreement dated August 5, 2021 (the "***Executive Agreement***"); and

WHEREAS, the Company desires to continue to employ Executive as its Chief Financial Officer, and to also employ the Executive as its Chief Business Officer, and the Executive desires to accept such employment and to perform the duties to the Company on the terms and conditions hereinafter set forth in this Amendment; and

WHEREAS, the Company and the Executive wish to amend the Executive Agreement as set forth in this Amendment.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other valid consideration, the sufficiency of which is acknowledged, the parties hereto agree as follows:

Agreement

1. **Amendment to Section 1(b).** Section 1(b) of the Executive Agreement is hereby amended by replacing the first paragraph in Section 1(b) in its entirety with the following:

   As of March 18, 2022 (the "***Amendment Effective Date***"), the Executive shall serve as the Chief Financial Officer and Chief Business Officer of the Company and shall have such powers and duties as customarily associated with those roles, and as may from time to time be prescribed by the Chief Executive Officer of the Company (the "***CEO***"), subject to the direction and control of the CEO. The Executive shall report to the CEO.

2. **Amendment to Section 2.**

   a. Section 2(a) is hereby replaced in its entirety as follows:

   Base Salary. As of the Amendment Effective Date, the Company will pay Executive, as compensation for the performance of the Executive's duties and obligations hereunder, salary at the rate of $510,000 per year, less applicable deductions. The Executive's salary shall be subject to annual review not later than March 31st of each year for possible increase by the Board or the Compensation Committee of the Board (the "***Compensation Committee***"), which may be adjusted from time to time. The base salary in effect at any given time is referred to herein

as "***Base Salary***." The Base Salary shall be payable in a manner that is consistent with the Company's usual payroll practices for its executive officers.

3. **Amendment to Appendix A.** Appendix A to the Executive Agreement is hereby amended by inserting the following underneath "Outside Activities":

Member of the Board of Directors of Akero Therapeutics, IVERIC Bio, and Ventus Therapeutics

4. The Company and the Executive further agree that this Amendment does not constitute grounds for "Good Reason" pursuant to Section 3(e) of the Executive Agreement, or otherwise constitute any trigger for the Company's payment of any severance benefits to Executive pursuant to the Executive Agreement.

5. Except as modified or amended in this Amendment, no other term or provision of the Executive Agreement is amended or modified in any respect. Executive remains employed "at will." The Executive Agreement and its exhibits, the Employee Proprietary Information and Inventions Assignment Agreement, and this Amendment, set forth the entire understanding between the parties with regard to the subject matter hereof and supersedes any prior oral discussions or written communications and agreements. This Amendment cannot be modified or amended except in writing signed by the Executive and an authorized officer of the Company.

The parties have executed this First Amendment to the Amended and Restated Employment Agreement of Jane Henderson on the day and year first written above.

Adagio Therapeutics, Inc.

/s/ David Hering

_____

David Hering
Interim CEO and Chief Operating Officer

Executive

/s/ Jane Henderson

_____

Jane Henderson

I hereby acknowledge and reaffirm my obligations pursuant to the Employee Proprietary Information and Inventions Assignment Agreement.

/s/ Jane Henderson

_____

Jane Henderson

Date: 3/25/2022

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-259008) of Adagio Therapeutics, Inc. of our report dated March 31, 2022 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 31, 2022

Exhibit 31.1

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

I, David Hering, certify that:

1. I have reviewed this Annual Report on Form 10-K of Adagio Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

By: /s/ David Hering, M.B.A.
David Hering, M.B.A.
Interim Chief Executive Officer and
Chief Operating Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Jane Pritchett Henderson, certify that:

1. I have reviewed this Annual Report on Form 10-K of Adagio Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 31, 2022

By: /s/ Jane Pritchett Henderson
Jane Pritchett Henderson
Chief Financial Officer and
Chief Business Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Adagio Therapeutics (the "Company") on Form 10-K for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 31, 2022

By: /s/ David Hering, M.B.A.
David Hering, M.B.A.
Interim Chief Executive Officer and
Chief Operating Officer
(Principal Executive Officer)

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Adagio Therapeutics (the "Company") on Form 10-K for the period ended December 31, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 31, 2022

By: /s/ Jane Pritchett Henderson
Jane Pritchett Henderson
Chief Financial Officer and
Chief Business Officer
(Principal Financial Officer)

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.