

PROSPECTUS

18,200,000 Shares



## Adagio Therapeutics, Inc.

COMMON STOCK

---

*Adagio Therapeutics, Inc. is offering 18,200,000 shares of common stock. This is our initial public offering and no public market exists for our common stock. The initial public offering price of our common stock is \$17.00 per share.*

---

*Our common stock has been approved for listing on the Nasdaq Global Market under the trading symbol “ADGI.”*

---

*We are an “emerging growth company” and a “smaller reporting company” as defined under U.S. federal securities laws and, as such, will be subject to reduced public company reporting requirements for this prospectus and future filings. See “Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company.”*

---

*Investing in our common stock involves risks. See “[Risk Factors](#)” beginning on page 13 of this prospectus.*

---

	<u>Per Share</u>	<u>Total</u>
Initial Public Offering Price	\$17.00	\$309,400,000
Underwriting Discounts and Commissions (1)	\$1.19	\$21,658,000
Proceeds, before expenses, to us	\$15.81	\$287,742,000

---

(1) We refer you to “Underwriting” for additional information regarding total underwriter compensation.

---

*We have granted the underwriters an option for a period of 30 days to purchase up to an additional 2,730,000 shares of our common stock.*

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

*The underwriters expect to deliver the shares of common stock against payment in New York, New York on or about August 10, 2021.*

---

Joint Book-Running Managers

MORGAN STANLEY

JEFFERIES

STIFEL

GUGGENHEIM SECURITIES

The date of this prospectus is August 5, 2021

## TABLE OF CONTENTS

	<u>Page</u>		<u>Page</u>
<a href="#">Prospectus Summary</a>	1	<a href="#">Executive Compensation</a>	172
<a href="#">Risk Factors</a>	13	<a href="#">Certain Relationships and Related Party Transactions</a>	184
<a href="#">Special Note Regarding Forward-Looking Statements</a>	83	<a href="#">Principal Stockholders</a>	190
<a href="#">Market and Industry Data</a>	85	<a href="#">Description of Capital Stock</a>	195
<a href="#">Use of Proceeds</a>	86	<a href="#">Shares Eligible for Future Sale</a>	201
<a href="#">Dividend Policy</a>	87	<a href="#">Material U.S. Federal Income Tax Consequences to Non-U.S. Holders</a>	204
<a href="#">Capitalization</a>	88	<a href="#">Underwriting</a>	208
<a href="#">Dilution</a>	90	<a href="#">Legal Matters</a>	217
<a href="#">Selected Consolidated Financial Data</a>	93	<a href="#">Experts</a>	217
<a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	95	<a href="#">Where You Can Find Additional Information</a>	217
<a href="#">Business</a>	113	<a href="#">Index to Consolidated Financial Statements</a>	F-1
<a href="#">Management</a>	162		

---

Neither we nor the underwriters have authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses we have prepared. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may provide you. We are offering to sell, and seeking offers to buy, shares of common stock only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the common stock.

For investors outside of the United States: we have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. Persons outside of the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside of the United States.

All trademarks, trade names and service marks appearing in this prospectus are the property of their respective owners. Solely for convenience, the trademarks and trade names in this prospectus may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert their rights thereto.

## Prospectus Summary

*This summary highlights, and is qualified in its entirety by, information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, especially the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes appearing elsewhere in this prospectus, before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to “we,” “us,” “our,” “the company,” “Adagio” and “Adagio Therapeutics” refer to Adagio Therapeutics, Inc.*

### Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential. We are developing our lead product candidate, ADG20, for the treatment and prevention 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 treatment and prevention options for years to come. We aim to address COVID-19 and future potential viral outbreaks by building a portfolio of antibodies with broadly neutralizing activity against multiple members of the coronavirus family or additional viruses with pandemic potential. Our portfolio of antibodies was discovered by Adimab, LLC, or Adimab, an industry leader in translating target hypotheses into therapeutically relevant antibodies with their proprietary platform, which has resulted in more than 385 antibody discovery programs, over 40 of which have advanced into clinical trials.

ADG20 is designed to be a potent, long-acting and broadly neutralizing antibody for both the treatment and prevention of COVID-19 as either a single or combination agent. Unlike other antibody-based therapies specifically targeting SARS-CoV-2, ADG20 has demonstrated in non-clinical studies an ability to neutralize SARS-CoV-2, including variants of concern, as well as a broad range of SARS-like viruses with neutralization potency at IC<sub>50</sub> (half maximal inhibitory concentrations) of approximately 0.01 mcg/mL or less in live-virus cellular assays. We believe this demonstrated *in vitro* neutralization activity will translate into the ability to conveniently deliver ADG20 as a single intramuscular, or IM, injection. We believe these and other attributes of ADG20 differentiate it from other antibodies that are either available under Emergency Use Authorization, or EUA, or in development to address COVID-19. We have completed enrollment in our first-in-human Phase 1 clinical trial of ADG20. Interim data demonstrated that ADG20 was well tolerated and displayed a pharmacokinetic profile consistent with an extended half-life monoclonal antibody, or mAb. Serum virus neutralizing antibody titers measured the day following administration of ADG20 were similar to or exceeded peak serum neutralizing antibody titers generated after two doses of mRNA or adenovirus-based COVID-19 vaccines. Based on these data, we are conducting two separate Phase 2/3 clinical trials: our STAMP trial to evaluate ADG20 for the treatment of COVID-19 and our EVADE trial to evaluate ADG20 for the prevention of COVID-19. Additionally, our portfolio includes multiple broadly neutralizing antibodies, including ADG10, for potential use with ADG20 as a combination therapy for the treatment and prevention of COVID-19 and future coronavirus outbreaks.

Over the past 20 years, three pathogenic novel coronaviruses have spilled over into the human population from animal reservoirs to cause outbreaks of deadly pneumonia, including COVID-19, severe acute respiratory syndrome, or SARS, and Middle East respiratory syndrome, or MERS. Most recently, SARS-CoV-2 has given rise to a global pandemic that swept rapidly throughout the world in 2020. Of significant current concern is the emergence of a number of SARS-CoV-2 variants with increased transmissibility 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) uneven global rollout of vaccinations; (2) ongoing vaccine hesitancy; (3) unknown duration of immunity and efficacy against current and future viral variants conferred by currently available vaccines; (4) uncertain impact of vaccines on transmission; and

(5) variable implementation of virus mitigation efforts, such as wearing masks and social distancing. As a result, our epidemiological modeling has suggested that as much as 50% of the global population may be susceptible to SARS-CoV-2 infection within three years. 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 SARS-like viruses that are capable of infecting humans.

In response to the ongoing pandemic, multiple agents have been discovered, developed and authorized at an unprecedented speed to address COVID-19. Several vaccines have been authorized for the prevention of COVID-19 under public health emergency guidelines both in the United States and abroad. In addition, some mAb therapies, either as a monotherapy or a combination cocktail, have been granted an EUA in the United States and India and are available for use as unauthorized products in certain EU member states for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. However, we believe additional solutions are required. The recent emergence of SARS-CoV-2 variants has attenuated *in vitro* neutralization activity of certain currently available mAbs. For example, the U.S. Food and Drug Administration, or the FDA, recently revoked the EUA for one of these mAbs due to its lack of *in vitro* activity against key variants of concern as a single agent and distribution of a second agent, bamlanivimab/etesevimab, has been paused in the United States due to data showing increased prevalence of two variants resistant to this product, the Gamma (P.1) and Beta (B.1.351) variants. Consistent with *in vitro* data showing more pronounced loss of neutralization activity for casirivimab and bamlanivimab/etesevimab against the Gamma variant compared to the Alpha variant, preliminary real-world use data from Italy suggest lower clinical efficacy for casirivimab/imdevimab and bamlanivimab/etesevimab against infections due to the Gamma 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. Additional factors that have limited use of mAbs include lack of awareness and education on appropriate use as well as perceived difficulty accessing treatment. We anticipate that these same limitations will apply to any IV-administered mAbs that may be authorized or approved for the prevention of COVID-19. Furthermore, in the setting of prevention, mAbs without sufficiently long half-lives will likely require frequent and periodic administration in order to achieve long-lasting protection.

#### **Our Approach to COVID-19 and Development of Coronavirus mAbs**

Our vision is to discover, develop and commercialize antibody-based solutions not only for the current COVID-19 pandemic but also to address future potential coronavirus outbreaks. To enable this vision, our discovery efforts are focused on broadly neutralizing antibodies that target conserved epitopes across multiple members of the coronavirus family. We believe that a mAb therapy with the following characteristics will have the potential to address the limitations of currently available treatment and prevention options for COVID-19 as well as future diseases that may arise from SARS-like viruses with pandemic potential:

- High potency and broad neutralizing activity to address SARS-CoV-2, including variants of concern, and additional SARS-like viruses, or sarbecoviruses;
- Multiple mechanisms of action, including direct virus neutralization by blocking viral entry into the host cell and elimination of infected host cells through innate immune effector activity to clear infection;
- Convenient outpatient administration as a single-dose IM injection; and
- Ability to provide both rapid and durable protection with potential protection against COVID-19 for up to one year.

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 differentiate our approach include:

- **Recognition of the importance of broadly neutralizing antibodies:** From the outset, 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 human angiotensin-converting enzyme 2, or hACE2, receptor.
- **Industry-leading B-cell mining, protein engineering and developability screening capabilities through our partnership with Adimab:** We leverage nature's solutions using Adimab's deep B-cell mining capabilities to isolate broadly neutralizing antibodies from a disease survivor of an earlier SARS infection. We then utilize Adimab's leading protein engineering capabilities to improve the potency, breadth and half-life of the antibody candidates we advance into preclinical development. We specifically engineer our antibodies to extend their half-lives without affecting Fc-mediated innate immune effector activity. In addition, we have access to Adimab's extensive suite of developability assays that allow for selection of lead candidates most likely to be readily manufactured and formulated for use in humans.
- **Reduced risk of clinical resistance:** We are developing antibodies that target conserved residues in the receptor-binding domain, or RBD, of the viral S protein. Importantly, these residues are distinct from those recognized by other SARS-CoV-2-specific antibodies that are currently available or in development. In addition, the residues that our antibodies target are not readily targeted by antibodies induced by natural infection, which are referred to as public antibodies. These two factors suggest that the residues our antibodies target are less likely to mutate, which we believe will reduce the risk of resistance to our antibodies.

#### **ADG20: Our Solution for the Treatment and Prevention of COVID-19**

ADG20, our lead product candidate, is designed to be a potent, broadly neutralizing antibody for both the treatment and prevention of COVID-19, including disease caused by variants, as either a single or combination agent. We believe ADG20 will have the following key clinical and commercial attributes:

- Broadly neutralizing activity across sarbecoviruses;
- Rapid onset of protection;
- Differentiated durability;
- Convenient, single-dose IM injection for use in the outpatient setting;
- Ability to both complement and supplement currently available COVID-19 vaccines, including for immunocompromised individuals;
- High titer, high yield manufacturing process;
- Standard refrigeration requirements to facilitate worldwide distribution and storage; and
- Long shelf life to enable stockpiling.

ADG20 has been evaluated in a series of *in vitro* and *in vivo* studies to demonstrate its breadth as well as safety and efficacy in various animal models. *In vitro* binding studies have demonstrated that ADG20 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. In *in vitro* studies, ADG20 has demonstrated neutralizing activity against SARS-CoV-2 and the 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, ADG20 demonstrated an ability to prevent and treat SARS-CoV-2 infection and associated disease as well as a prolonged serum half-life.

We have completed enrollment in our first-in-human Phase 1 clinical trial in healthy volunteers. Interim data demonstrated that ADG20 was well tolerated and displayed a pharmacokinetic profile consistent with an extended half-life mAb. Serum virus neutralizing antibody titers measured the day following administration of ADG20 were similar to or exceeded peak serum neutralizing antibody titers generated after two doses of mRNA or adenovirus-based COVID-19 vaccines. For the treatment of mild to moderate COVID-19 in patients at high risk of disease progression, we are conducting our STAMP trial, a combined Phase 2/3 global clinical trial designed to provide a path to applying for EUA and/or filing a BLA for marketing approval in 2022, and commercial launch thereafter, if ADG20 is approved. We may not meet our time frames for submission for an EUA or BLA, and if we do meet such timelines, there is no guarantee the FDA would approve our submission, or on the time frame we have indicated. For the prevention of COVID-19, we are conducting our EVADE trial, a combined Phase 2/3 global clinical trial, in both post-exposure and pre-exposure populations. 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 prior to the onset of significant immune pathology is likely to provide the greatest benefit to patients.

**ADG20 for Treatment and Prevention of COVID-19**

	ADG20 Target Populations					
	Uninfected	Asymptomatic or Presymptomatic	Mild Illness	Moderate Illness	Severe Illness	Critical Illness
SARS-CoV-2 RNA Testing	Negative	Positive	Positive	Positive	Positive	Positive
Clinical Features	No symptoms	No symptoms	Mild symptoms (eg, fever, cough, change in taste or smell); no shortness of breath	Clinical or radiographic evidence of pneumonia; oxygen saturation $\geq$ 94%	Oxygen saturation $<$ 94%; elevated respiratory rate; extensive lung involvement	Respiratory failure, shock, multiple organ dysfunction or failure
Proposed Disease Pathogenesis		Viral Replication			Inflammation	

If our STAMP and EVADE trials are successful, we believe ADG20 has the potential to be approved for both the treatment and prevention of COVID-19 in the United States, potentially preceded by an EUA for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. Importantly, given the global impact of COVID-19, we also plan to seek approvals outside the United States. In addition, we are developing a clinical plan to support the use of ADG20 in the pediatric population for both the treatment and prevention of COVID-19.

**Additional Broadly Neutralizing Antibodies and Discovery Programs Beyond ADG20**

We are currently evaluating additional broadly neutralizing antibodies, such as ADG10, for potential use in combination with ADG20 for COVID-19. We believe the incorporation of a second broadly neutralizing antibody that targets a distinct viral epitope from the epitope targeted by ADG20 will ensure long-lasting product activity against COVID-19 as new variants of SARS-CoV-2 emerge, as well as against future potential outbreaks of disease that may arise from additional SARS-like viruses with pandemic potential. In addition, we plan to leverage the robust antibody discovery and development capabilities that have enabled our expedited advancement of ADG20 into clinical trials to develop therapeutic or preventative options for other respiratory viral infections, such as additional coronaviruses and seasonal and pandemic 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.

## **Our Strategy**

Our goal is to develop and commercialize differentiated antibody-based solutions with broadly neutralizing activity for the treatment and prevention of diseases caused by SARS-CoV-2, its variants and additional SARS-like viruses with pandemic potential. In order to achieve this goal, our strategy involves executing on the following key elements:

- Leverage our team’s collective expertise in development, manufacturing and commercialization to efficiently bring ADG20 to patients.
- Complete development and obtain global approval for our lead product candidate, ADG20, for both the treatment and prevention of COVID-19.
- Successfully commercialize ADG20, if approved, through our own organization in the United States and Europe, and partners in the rest of the world.
- Continue to secure additional manufacturing capacity with trusted contract development and manufacturing organization, or CDMO, partners to enable a worldwide commercial launch.
- Develop additional antibodies for use in potential combination with ADG20 to address future potential variants of SARS-CoV-2 and other sarbecovirus outbreaks.
- Leverage relationships with Adimab and academic institutions to discover additional antibody-based solutions to address coronavirus and influenza infections.

## **Our History and Team**

We were founded in June 2020 to develop a portfolio of anti-coronavirus antibodies discovered by Adimab for both the treatment and prevention of COVID-19 and future coronavirus outbreaks. Our founding scientists discovered ADG20, our lead product candidate, while working at Adimab, an industry leader in translating target hypotheses into therapeutically relevant antibodies. The Adimab platform has been used in more than 385 antibody discovery and optimization programs, more than 40 of which have advanced into clinical trials, including five programs in pivotal clinical trials. In order to maximize ADG20’s potential and to ensure its development and commercialization with appropriate infectious disease resources and development expertise, 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 mAbs. Many of our team members have held senior positions at companies such as Cubist Pharmaceuticals, Inc., Vir Biotechnology Inc., Adimab, Biogen and Ironwood Pharmaceuticals, among others. 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.

Since our inception, we have raised approximately \$470 million of capital from leading institutional healthcare investors and our partners.

## **Risks Associated with Our Business**

Our business is subject to numerous risks that you should be aware of before making an investment decision. These risks are described more fully in the section titled “Risk Factors” and include, among others:

- 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.

## Table of Contents

- Even if this offering is successful, 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 recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern.
- 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.
- Because ADG20 and any future product candidates represent novel approaches to the 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 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.
- 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 treat symptomatic 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.
- 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 the addressable markets for our product candidates.
- ADG20 and our other monoclonal antibody product candidates may face significant competition from vaccines and other treatments for COVID-19 that are currently available or in development.
- 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 and officers 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 have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.

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

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or the JOBS Act. As such, we may take advantage of certain exemptions from various reporting requirements that are otherwise applicable to public companies. These exemptions include, but are not limited to:

- 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 in this prospectus;
- 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 may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering. However, if prior to the end of such five-year period, (i) our annual gross revenue exceeds \$1.07 billion, (ii) we issue more than \$1.0 billion of non-convertible debt in the previous three-year period or (iii) we become a “large accelerated filer” (as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act), we will cease to be an emerging growth company prior to the end of such five-year period. We will be deemed to be a “large accelerated filer” at such time that we (a) have an aggregate worldwide market value of our common stock held by non-affiliates of \$700.0 million or more as of the last business day of our most recently completed second fiscal quarter, (b) have been required to file annual and quarterly reports under the Exchange Act for a period of at least 12 months and (c) have filed at least one annual report pursuant to the Exchange Act.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus forms a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

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. We have elected not to “opt out” of the exemption for the delayed adoption of certain accounting standards, and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standards 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.

We are also a “smaller reporting company” as defined under the Securities Exchange Act. We may continue to be a smaller reporting company for so long as either (i) the market value of our common stock held by non-affiliates is less than \$250 million as of the last business day of our most recently completed second fiscal quarter or (ii) our annual revenue was less than \$100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than \$700 million as of the last business day of our most recently completed second quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and have reduced disclosure obligations regarding executive compensation, and, similar to emerging growth companies, if we are a smaller reporting company with less than \$100 million in annual revenue, we would not be required to obtain an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

#### **Corporate Information**

We were incorporated under the laws of the State of Delaware in June of 2020. Our principal executive offices are located at 303 Wyman Street, Suite 300, Waltham, MA 02451 and our telephone number is (781) 819-0080. Our website address is [adagiotx.com](http://adagiotx.com). The information contained on, or accessible through, our website is not incorporated by reference into this prospectus, and you should not consider any information contained in, or that can be accessed through, our website as part of this prospectus or in deciding whether to purchase our common stock. We have included our website in this prospectus solely as an inactive textual reference.

## THE OFFERING

Common stock offered by us	18,200,000 shares.
Common stock to be outstanding immediately after this offering	108,515,660 shares (or 111,245,660 shares if the underwriters exercise in full their option to purchase up to 2,730,000 additional shares).
Option to purchase additional shares offered by us	We have granted the underwriters an option for a period of 30 days to purchase up to 2,730,000 additional shares of common stock.
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$283.9 million, or approximately \$327.1 million if the underwriters exercise in full their option to purchase up to 2,730,000 additional shares of common stock, based on the initial public offering price of \$17.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, to fund clinical development, manufacturing supply and initial commercialization costs for ADG20, and the remainder for working capital and other general corporate purposes, including development of additional programs in our pipeline. See the section titled “Use of Proceeds” for additional information.</p>
Risk factors	You should read the section titled “Risk Factors” for a discussion of factors you should consider carefully, together with all the other information included in this prospectus, before deciding to invest in our common stock.
Nasdaq Global Market symbol	“ADGI”

The number of shares of our common stock to be outstanding after this offering is based on 90,315,660 shares of our common stock outstanding as of March 31, 2021, assuming the automatic conversion of all outstanding shares of our preferred stock, including 4,296,550 shares of Series C preferred stock issued in April 2021, into an aggregate of 84,722,420 shares of common stock upon the closing of this offering, and excludes:

- 6,000 shares of our common stock issued subsequent to March 31, 2021;
- 5,366,070 shares of our common stock issuable upon the exercise of options outstanding as of March 31, 2021 under our 2020 Equity Incentive Plan, or the 2020 Plan, at a weighted-average exercise price of \$2.49 per share (which does not include options to purchase an aggregate of 11,427,020 shares of our common stock, at a weighted-average exercise price of \$10.86 per share, that were granted subsequent to March 31, 2021);

## [Table of Contents](#)

- 11,860,995 shares of our common stock available for future issuance as of March 31, 2021 under the 2020 Plan, which such shares ceased to be available for issuance under the 2020 Plan at the time our 2021 Equity Incentive Plan, or the 2021 Plan, became effective and became available for issuance under the 2021 Plan;
- 6,434,485 additional shares of our common stock available for future issuance under our 2020 Plan, which was amended subsequent to March 31, 2021 to increase the shares available under the plan, which such shares ceased to be available for issuance under the 2020 Plan at the time our 2021 Plan became effective and became available for issuance under the 2021 Plan;
- 11,413,572 shares of our common stock that became available for future issuance under the 2021 Plan, which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan; and
- 1,342,773 shares of our common stock that became available for future issuance under our 2021 Employee Stock Purchase Plan, or the 2021 ESPP, which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 ESPP.

Unless otherwise indicated, all information contained in this prospectus, including the number of shares of common stock that will be outstanding after this offering, assumes or gives effect to:

- the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 84,722,420 shares of our common stock, which will occur upon the closing of this offering;
- a five-for-one split of our common stock effected on July 30, 2021;
- the filing and effectiveness of our amended and restated certificate of incorporation and the adoption of our amended and restated bylaws immediately prior to the completion of this offering;
- no exercise of the outstanding options referred to above after March 31, 2021; and
- no exercise by the underwriters of their option to purchase additional shares of our common stock.

## SUMMARY CONSOLIDATED FINANCIAL DATA

You should read the following summary consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the “Selected Consolidated Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. We have derived the consolidated statement of operations data for the period from June 3, 2020 (inception) to December 31, 2020 from our audited consolidated financial statements appearing at the end of this prospectus. The consolidated statement of operations data for the three months ended March 31, 2021 and the consolidated balance sheet data as of March 31, 2021 have been derived from our unaudited consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in any future period.

	Period from June 3, 2020 (Inception) to December 31, 2020	Three Months Ended March 31, 2021
(in thousands, except per share data)		
<b>Consolidated Statement of Operations Data:</b>		
Operating expenses:		
Research and development <sup>(1)</sup>	\$ 21,992	\$ 34,032
Acquired in-process research and development <sup>(2)</sup>	40,125	1,000
Selling, general and administrative	3,210	3,677
Total operating expenses	<u>65,327</u>	<u>38,709</u>
Loss from operations	<u>(65,327)</u>	<u>(38,709)</u>
Other income:		
Interest income	8	9
Total other income	<u>8</u>	<u>9</u>
Net loss	<u>\$ (65,319)</u>	<u>\$ (38,700)</u>
Net loss per share attributable to common stockholders, basic and diluted <sup>(3)</sup>	<u>\$ (18.10)</u>	<u>\$ —</u>
Weighted-average common shares outstanding, basic and diluted <sup>(3)</sup>	<u>3,608</u>	<u>—</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) (3)	<u>\$ (1.25)</u>	<u>\$ (0.61)</u>
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited) <sup>(3)</sup>	<u>52,167</u>	<u>63,240</u>

(1) Includes related-party amounts of \$0.6 million for the period from June 3, 2020 (inception) to December 31, 2020 and \$0.2 million for the three months ended March 31, 2021. See Note 6 to our consolidated financial statements appearing at the end of this prospectus.

(2) Includes related-party amounts of \$39.9 million for the period from June 3, 2020 (inception) to December 31, 2020 and \$1.0 million for the three months ended March 31, 2021. See Note 6 to our consolidated financial statements appearing at the end of this prospectus.

(3) See Note 13 to our consolidated financial statements appearing at the end of this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders and the “Selected Consolidated Financial Data” section of this prospectus for details on the calculation of unaudited basic and diluted pro forma net loss per share attributable to common stockholders.

## [Table of Contents](#)

	As of March 31, 2021		
	Actual	Pro Forma(2) (in thousands)	Pro Forma As Adjusted(3)
<b>Consolidated Balance Sheet Data:</b>			
Cash and cash equivalents	\$ 91,247	\$ 426,746	\$ 710,738
Working capital(1)	66,197	401,696	685,638
Total assets	94,874	430,373	714,260
Convertible preferred stock	169,548	—	—
Total stockholders' equity (deficit)	(103,362)	401,685	685,627

(1) We define working capital as current assets less current liabilities.

(2) The pro forma consolidated balance sheet data give effect to (i) our issuance and sale in April 2021 of 4,296,550 shares of our Series C preferred stock for gross proceeds of \$335.5 million and (ii) the automatic conversion of all outstanding shares of our preferred stock, including our Series C preferred stock, into an aggregate of 84,722,420 shares of common stock upon the closing of this offering.

(3) The pro forma as adjusted consolidated balance sheet data give further effect to our issuance and sale of 18,200,000 shares of our common stock in this offering at the initial public offering price of \$17.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

## RISK FACTORS

*Investing in our common stock involves a high degree of risk. You should consider carefully the risks and uncertainties described below, together with all of the other information in this prospectus, including our financial statements and related notes, before deciding whether to purchase shares of our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the price of our common stock could decline, and you could lose part or all of your investment.*

### 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 \$65.3 million for the period from June 3, 2020 (inception) to December 31, 2020 and \$38.7 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of \$104.0 million. Since our inception, we have financed our operations with gross proceeds of \$465.4 million raised in our private placements of preferred stock, including the sale of our Series C preferred stock in April 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 ADG20, including advancement into 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 Emergency Use Authorization, 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 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;
- develop, establish and validate our commercial-scale cGMP manufacturing process;
- 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;

## Table of Contents

- 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. 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.

***Even if this offering is successful, 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



## Table of Contents

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 March 31, 2021, we had cash and cash equivalents of \$91.2 million. In addition, in April 2021, we received gross proceeds of \$335.5 million from sales of our Series C preferred stock. We believe that the anticipated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements into the first quarter of 2023. 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 the net proceeds from this offering to fund clinical development, manufacturing supply and initial commercialization costs for ADG20, and the remainder for working capital and other general corporate purposes, including development of additional programs in our pipeline. The net proceeds from this offering, together with our existing cash and cash equivalents, 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 AGD20 and our other product candidates;
- the scope, progress, results and costs of non-clinical studies, preclinical development, laboratory testing and clinical trials for ADG20 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 ADG20 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;

## Table of Contents

- 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.

***Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern.***

Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern. In our financial statements for the period from June 3, 2020 (inception) to December 31, 2020, we concluded that our recurring losses from operations and need for additional financing to fund future operations raise substantial doubt about our ability to continue as a going concern. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial

## Table of Contents

statements for the period from June 3, 2020 (inception) to December 31, 2020 with respect to this uncertainty. Our ability to continue as a going concern will require us to obtain additional funding. If we are unable to obtain sufficient funding, our business, prospects, financial condition and results of operations will be materially and adversely affected, and we may be unable to continue as a going concern. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, limit, reduce or terminate our product development or future commercialization efforts of one or more of our product candidates, or may be forced to reduce or terminate our operations. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. After this offering, in our own required quarterly assessments, we may again conclude that there is substantial doubt about our ability to continue as a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms, if at all.

### **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 ADG20, our lead monoclonal antibody product candidate. We have also advanced ADG20 into global pivotal trials for the treatment and prevention of COVID-19, including in countries with high rates of resistant variants. We have initiated conduct of our first prospective, randomized, multi-center clinical trials, 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, 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 ADG20 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 U.S. Food and Drug Administration, or 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;

## Table of Contents

- 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;
- 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 ADG20 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 treatment and prevention of COVID-19, including due to the continuation 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 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 ADG20 and any future product candidates represent novel approaches to the 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 new disease, the treatment and prevention of which is not yet well understood. Although monoclonal antibody products have been used in the treatment of many indications, to date, the FDA has not yet approved the use of any monoclonal antibodies to treat COVID-19, although the FDA has issued an EUA for several monoclonal antibody products for the treatment of COVID-19 in patients at high risk of disease progression, including bamlanivimab, casirivimab/imdevimab, bamlanivimab/etesevimab and sotrovimab. Because this is a relatively new and expanding area of novel therapeutic interventions, there are many

## Table of Contents

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 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 to support marketing approval.

In addition, the FDA may take longer than usual to come to a decision on any BLA that we submit and may ultimately determine that there is insufficient data, information or experience with our product candidates to support an approval decision. The FDA 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 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 treatment or prevention of symptomatic COVID-19. Even if we are able to identify and develop such antibodies, we cannot ensure that such product candidates will achieve marketing approval to safely and effectively treat or prevent 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

## Table of Contents

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 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

## Table of Contents

all. We may experience numerous unforeseen events before, during or as a result of 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;
- 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;
- having an insufficient 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, 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;

## Table of Contents

- 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 ADG20;
- 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.



## [Table of Contents](#)

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.

***There can be no assurance 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 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 or other similar authorization or, if we do apply, that we will be able to obtain such authorization. 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 arise or if we fail to comply with the conditions of authorization. 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 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 only limited discussions with the FDA and the Medicines and Healthcare products Regulatory Agency regarding clinical development programs or regulatory approval for any product candidate within the United States and United Kingdom, respectively. In addition, we have had no discussions with other comparable foreign authorities regarding clinical development programs or regulatory approval for any product candidate outside of those jurisdictions.

## Table of Contents

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;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers and testing laboratories with which we contract for clinical and commercial supplies; 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

## Table of Contents

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 potent for their intended uses. In addition, the FDA may determine that antibody monotherapy products are not sufficient and that combination antibody therapies should become the standard of care.

## Table of Contents

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 expectations for the product candidate, if approved. These side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from monoclonal antibody therapy, as with our ADG20 product candidate, are not normally encountered in the general patient population and by medical personnel.

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 treat symptomatic 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 treat symptomatic COVID-19. To date, the FDA has

## Table of Contents

not yet approved any monoclonal antibodies to treat or prevent COVID-19, although the FDA has issued an EUA for several monoclonal antibody products for the treatment of COVID-19 in patients at high risk of disease progression, including bamlanivimab, casirivimab/imdevimab, bamlanivimab/etesevimab and sotrovimab. 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, which could 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.

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 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;
- 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, 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;

## Table of Contents

- 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 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 ADG20 for the treatment and prevention 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 intend to conduct 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 treatment and prevention of COVID-19. The severity of the global pandemic, the availability, administration and acceptance of vaccines and monoclonal antibodies 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.



## Table of Contents

Although our planned clinical trials have not been materially delayed by the COVID-19 pandemic to date, in December 2020 shipment of ADG20 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;
- 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 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;
- 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 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, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global COVID-19 pandemic continues to rapidly evolve. 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 at the time of this prospectus, such as the ultimate geographic spread of the disease, 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



## Table of Contents

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 SARS-CoV-2 variants could reduce the activity and effectiveness of ADG20 as a potential treatment for or prevention of symptomatic COVID-19.***

Multiple variants of the virus that causes COVID-19 have been documented in the United States and globally during this pandemic. Although we have shown in pre-clinical studies that ADG20 has the potential to broadly neutralize SARS-CoV-2 and the predominantly circulating variants, new SARS-CoV-2 variants could be less impacted by ADG20 and its mechanism of action, or the results shown in pre-clinical studies may not be replicated in clinical studies. This would significantly and adversely affect our ability to obtain authorization or approval of and to commercialize ADG20.

***We may develop ADG20 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 ADG20 and future product candidates for use in combination with one or more currently authorized or approved therapies to treat symptomatic 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 ADG20 as a monotherapy treatment.

We may also evaluate ADG20 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 ADG20 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 ADG20 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 have a negative effect on global economic conditions, financial markets and our business.***

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. Negotiations between the United Kingdom and the European Union are expected to continue in relation to the customs and trading relationship between the United Kingdom and the European Union following the expiry of the Transition Period.

## [Table of Contents](#)

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, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the United Kingdom will no longer be covered by the centralized procedures for obtaining European Union-wide marketing authorizations from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products will be required in the United Kingdom, the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would 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. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the European Union, or we may incur expenses in establishing a manufacturing facility in the European Union in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or the European Union for our product candidates, or incur significant additional expenses to 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 foreign regulatory authorities. If we or our manufacturers were to fail to comply with the FDA, EMA or other regulatory authority, 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 using technically complex processes 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, may lead to an inability to

## Table of Contents

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 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;
- 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, 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 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 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 a manufacturing facility 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 if the facilities of any of our CDMOs do not pass such audit or inspections. Certain of our CDMO's facilities are or may be under construction and have not completed installation of equipment for and establishment of routine manufacturing and testing operations and have not yet been inspected by regulatory authorities. If any of our CDMO's facilities do not pass a pre-approval plant inspection, FDA or EMA approval of the products will not be granted.

## Table of Contents

The regulatory authorities also may, at any time following approval of a product for sale, inspect or audit 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 produce clinical and commercial supplies of our product candidates.***

We are currently manufacturing material for our product candidates in partnership with a CDMO. We do not own or operate any facilities for product manufacturing, storage and distribution or testing. We are dependent on third parties to manufacture the clinical and commercial supplies of our current and any future product candidates. We have established a relationship with WuXi to produce material to support our clinical development program and our initial commercial supply for our products, if approved. We have not yet fully manufactured our product candidates on a commercial scale, and we do not yet have sufficient information to reliably estimate the cost of the commercial manufacturing of our product candidates. 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 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

## Table of Contents

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 ADG20 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 ADG20 and will rely on WuXi for commercial supply of ADG20. 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.

In July 2021, we entered into a license agreement with Biocon Biologics Limited, or Biocon, to combat the ongoing COVID-19 crisis in southern Asia. Under the license agreement, we will provide Biocon materials and know-how to manufacture and commercialize an antibody treatment based on ADG20 in India and select emerging markets. Biocon's ability to successfully manufacture in those territories may be restricted by foreign regulatory requirements.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- inability to access sufficient 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 or that they 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, 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 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.

## Table of Contents

***We depend on sole-source third-party suppliers for materials that are necessary for the conduct of preclinical studies and manufacture 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 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 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 we change suppliers or manufacturers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. 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, 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 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 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

## Table of Contents

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 facility itself. Any contamination could adversely affect our ability to produce 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 of our product candidates could adversely impact or disrupt the commercial manufacturing or the production of 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 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;



## Table of Contents

- 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 ADG20 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 ADG20 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 ADG20 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 the addressable markets for our product candidates.***

Our projections of the number of people who are candidates to receive COVID-19 treatments and preventatives 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, may not be otherwise amenable to treatment with our product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect 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 treatments for or widespread immunity to COVID-19, could reduce the total addressable market for our lead product candidate for the treatment and prevention of COVID-19. Similarly, if new SARS-CoV-2 variants are less impacted by ADG20 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 ADG20, 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 prospectus may turn out to be inaccurate. Further, the data and statistical information used in this prospectus, 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

## Table of Contents

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.

### ***ADG20 and our other monoclonal antibody product candidates may face significant competition from vaccines and other treatments for COVID-19 that are currently available or in development.***

Many biotechnology and pharmaceutical companies are developing treatments 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 therapeutics and vaccines for the treatment or prevention of COVID-19 developed or marketed by other companies, many of which are large, established biotechnology and pharmaceutical companies. 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 treatment we may develop could face significant competition. If any other company develops treatments more rapidly or effectively than we do, develops a treatment that becomes the standard of care, develops a treatment at a lower cost or is more successful at commercializing an approved therapeutic, we may not be able to successfully commercialize ADG20 for the treatment and prevention of symptomatic COVID-19, even if approved, or compete with other treatments 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. 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 treatment and prevention guidelines from organizations such as the 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.

## Table of Contents

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, 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 ADG20 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 ADG20 to their formularies, significantly reducing demand for ADG20, 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.

### ***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

## [Table of Contents](#)

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 ADG20 for the treatment and prevention 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 treatment and prevention of COVID-19, including guidance regarding the use of monoclonal antibodies in these indications. If ADG20 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 ADG20 to their formularies, significantly reducing demand for ADG20, 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

## Table of Contents

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 ADG20 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.***

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are 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. The risk of a security 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. If such an 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.

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.

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.

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 data breach, disruption or security incident were to result in any loss, destruction, or alteration of, damage, unauthorized access to or inappropriate or unauthorized disclosure or dissemination of, our data, including personal data, or other information that is processed or maintained on our behalf, we could be exposed to litigation and governmental investigations and inquiries, the further development

and commercialization of our product candidates could be delayed and we could be subject to significant fines or penalties for any noncompliance with applicable state, federal and foreign privacy and security laws, rules, regulations and standards.

***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 consolidated annual worldwide gross revenue), 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



## Table of Contents

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 February 19, 2021 the European Commission published its draft decision finding the United Kingdom to be adequate under the GDPR, though it remains unclear whether the European Commission will formally adopt an adequacy decision with respect to the United Kingdom. In the absence of such decision, after the expiry of the additional transition period we may need to put in place additional safeguards for transfers of personal data from the European Union to the United Kingdom, such as standard contractual clauses approved by the European Commission.

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, the California Privacy Rights Act, or the CPRA, recently passed in California and 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.

With the GDPR, CCPA, CPRA 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



## Table of Contents

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 ADG20, 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

## Table of Contents

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 ADG20 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.

## Table of Contents

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

## [Table of Contents](#)

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. Although we own a number of pending patent applications that have not yet issued as patents, we do not own or license any issued patents with claims directed to our product candidates, including ADG20, and we may not be successful in prosecuting our filed patent applications. Accordingly, there can be no assurance that we will be able to obtain patent protection for any of our product candidates, including ADG20. 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,

## Table of Contents

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,

## Table of Contents

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



## [Table of Contents](#)

materially and adversely affected. For more information on the Adimab Assignment Agreement, see the section titled “Business—Licensing, Collaborations and Partnerships—Assignment and License Agreement with Adimab.” For more information regarding our relationship with Adimab, see the section titled “Certain Relationships and Related Party Transactions.”

***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;



## Table of Contents

- 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

## Table of Contents

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

## [Table of Contents](#)

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 ADG20 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

## Table of Contents

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 ADG20 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 ADG20, and a third party may claim that our development or commercialization of ADG20 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 ADG20, 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 ADG20, 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 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 and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent 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 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 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 ADG20 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

## Table of Contents

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

## Table of Contents

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



## Table of Contents

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 ADG20 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. 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. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand 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;

## Table of Contents

- 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,

## Table of Contents

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, 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) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives; 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

## Table of Contents

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 ADG20 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 ADG20 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 ADG20 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.

## Table of Contents

If we fail to comply with applicable regulatory requirements following approval of ADG20 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 ADG20 or any future product candidates and harm our business, financial condition, results of operations and prospects.

***Even if we obtain 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.

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.

## [Table of Contents](#)

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 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." On December 14, 2018, a judge for the United States District Court for the Northern District of Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Act. Additionally, on December 18, 2019, the United States Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The United States Supreme Court is currently reviewing this case, although it is unclear when a decision will be made. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. Although the U.S. Supreme Court has not yet ruled on the constitutionality of the ACA, 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 will remain 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, will remain in effect through 2030 unless additional Congressional action is taken. However, COVID-19 relief legislation suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2021. 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

## Table of Contents

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 also released a final rule on September 24, 2020 providing guidance 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 implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. 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 which was also delayed pending review by the Biden administration until January 1, 2023. 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. On December 28, 2020, the United States District Court for the Northern District of California issued a nationwide preliminary injunction against implementation of the interim final rule. The likelihood of implementation of any of the other Trump administration reform initiatives is uncertain, particularly in light of the recent U.S. presidential election.

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.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. For example, the results of the 2020 U.S. Presidential election may impact our business and industry. The Trump administration took several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. It is difficult to predict whether or how these requirements will be interpreted and implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for ADG20 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 ADG20 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 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 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 and officers 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.***

Tillman U. Gerngross, Ph.D., our co-founder, Chief Executive Officer and a member of our board of directors, is a co-founder, the currently serving Chief Executive Officer and a member of the board of directors of Adimab, and also serves as an officer and/or Chairman of three additional private companies, Venture Partner at one additional private company and Chairman of one public company. 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. As a result, these directors and executive officers 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 own equity interests in Adimab, which represent a significant portion of these individuals’ net worth. 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.

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

Our executive officers, directors, five percent stockholders and their affiliates beneficially own approximately 80.7% of our voting stock as of August 2, 2021. Therefore, these stockholders, and in particular,

## Table of Contents

our largest stockholder, Adimab, will have the ability to influence us through their ownership positions. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

***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 30.8% of the voting power of our outstanding common stock as of August 2, 2021 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 and officers may have actual or potential conflicts of interest with us because of their positions or affiliations with Adimab or their equity ownership in Adimab. Tillman Gerngross, co-founder and Chief Executive Officer and member of the board of directors of 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 as our executive officers 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 expect to 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.***

As of August 2, 2021, we had 68 employees. As our development progresses, we expect to experience significant 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 anticipated 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.

## Table of Contents

***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 This Offering, Ownership of Our Common Stock and Our Status as a Public Company**

***An active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock at or above the initial offering price, if at all.***

Prior to this offering, there has been no public market for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters and may not be indicative of the price at which our common stock will trade after the closing of this offering. Although our common stock has been approved for listing on the Nasdaq Global Market, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchased in this offering at an attractive price or at all.

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

Our stock price may be volatile. 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 ADG20 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 ADG20 or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory

## Table of Contents

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 ADG20 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.

## Table of Contents

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.

***If you purchase shares of our common stock in this offering, you will suffer immediate dilution of your investment.***

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock after this offering. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on the initial public offering price of \$17.00 per share, you will experience immediate dilution of \$10.68 per share, representing the difference between our pro forma as adjusted net tangible book value per share as of March 31, 2021, after giving effect to this offering, and the initial public offering price.

In addition, as of March 31, 2021, we had outstanding stock options to purchase an aggregate of 5,366,070 shares of common stock at a weighted-average exercise price of \$2.49 per share. To the extent any of these outstanding options are exercised, there will be further dilution to investors in this offering. See "Dilution."

***We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.***

We identified a material weakness in our internal control over financial reporting that existed as of March 31, 2021. 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 consolidated financial statements will not be prevented or detected on a timely basis.

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 consolidated financial statements. Additionally, this material weakness could result in misstatements of the aforementioned account balances or disclosures that would result in a material misstatement of our annual or interim consolidated financial statements that would not be prevented or detected.

In order to remediate this material weakness, we intend to design and implement a control during interim periods related to the completeness and accuracy of the contract manufacturing accrual process.

We cannot assure that the measures we have taken to date, and actions we may take in the future, will be sufficient to remediate the control deficiency that led to this material weakness in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or

## Table of Contents

any future material weaknesses in our internal control over financial reporting, or we identify any additional material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, potentially resulting in restatements of our consolidated financial statements; we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports and applicable Nasdaq listing requirements; investors may lose confidence in our financial reporting; and our stock price may decline as a result.

***If we are unable to design and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock may decline.***

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 this offering, we intend to begin the process of documenting, reviewing and improving our internal control over financial reporting for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting.

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. If we fail to remediate our identified material weakness, or identify additional material weaknesses, in our internal control over financial reporting; if we are unable to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner; or if we are unable to assert that our internal control over financial reporting is effective, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could decline, and we could also become subject to investigations by the stock exchange on which our common stock is listed, the Securities and Exchange Commission, or 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 will be 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 restricted from immediate resale but may be sold into the market in the near future. 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.

## Table of Contents

Upon the closing of this offering, we will have outstanding 108,515,660 shares of common stock, after giving effect to the automatic conversion of our outstanding preferred stock into 84,722,420 shares of our common stock, and assuming no exercise of outstanding options to purchase shares of our common stock. Of these shares, the 18,200,000 shares sold in this offering will be freely tradable and substantially all of the additional shares of common stock will be available for sale in the public market beginning 180 days after the date of this prospectus following the expiration of lock-up agreements between some of our stockholders and the underwriters. Morgan Stanley & Co. LLC and Jefferies LLC may release these stockholders from their lock-up agreements with the underwriters at any time and without notice, which would allow for earlier sales of shares in the public market.

In addition, promptly following the closing of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, registering the issuance of 36,417,895 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, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Additionally, after this offering, the holders of an aggregate of 84,722,420 shares of our common stock, or their transferees, will 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 to be in effect upon the closing of this offering 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<sup>2</sup>/<sub>3</sub>% 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



## Table of Contents

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 5% or more of our common stock and their respective affiliates beneficially own 80.7% of our outstanding common stock as of August 2, 2021. 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 this 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 in this prospectus;
- 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 have taken advantage of the reduced reporting burdens in this prospectus. In particular, in this prospectus, we have provided only two years of audited financial statements and we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. 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.

## Table of Contents

***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.” 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 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 will have broad discretion in the use of proceeds from this offering and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.***

We will have broad discretion over the use of proceeds from this offering. You may not agree with our decisions, and our use of the proceeds may not yield any return on your investment. We expect to use the net proceeds to us from this offering, together with our existing cash and cash equivalents, to fund clinical development, manufacturing supply and initial commercialization costs for ADG20, and the remainder for working capital and other general corporate purposes, including development of additional programs in our pipeline. See “Use of Proceeds.” In addition, we may use a portion of the proceeds from this offering to pursue our strategy to in-license or acquire additional product candidates. Our failure to apply the net proceeds from this offering 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 these net proceeds. You will not have the opportunity to influence our decisions on how to use our net proceeds from this offering.

***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;

## Table of Contents

- 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, 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.

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 will 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

## Table of Contents

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, 2020, we had U.S. federal net operating loss, or NOL, carryforwards of \$24.4 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, 2020, we had state NOL carryforwards of \$3.7 million, which may be available to reduce future taxable income, of which \$0.3 million have an indefinite carryforward period while the remaining \$3.4 million begin to expire in 2040. As of December 31, 2020, we also had U.S. federal and state research and development tax credit carryforwards of \$0.1 million and \$16,000, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2040 and 2035, 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 are limited. It is uncertain how various states will respond to the Tax Act and 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. The completion of this 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 experience ownership changes as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs 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.

### ***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

## Table of Contents

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. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the 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 could adversely affect our business, financial condition or results of operations.***

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. 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. Furthermore, a severe or prolonged economic downturn, including a recession or depression resulting from the current COVID-19 pandemic or political disruption could result in a variety of risks

---

[Table of Contents](#)

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.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. The forward-looking statements are contained principally in the sections titled “Prospectus Summary,” “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” “Business” and elsewhere in this prospectus. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “estimate,” “believe,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions intended to identify statements about the future. These statements speak only as of the date of this prospectus and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- the timing, progress and results of our preclinical studies and clinical trials of ADG20 and any future product candidates, including statements regarding the timing of our planned IND submissions, initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing of any submission of filings for regulatory approval of, and our ability to obtain and maintain regulatory approvals for, our current and future product candidates;
- our manufacturing capabilities and strategy, including the scalability and commercial viability of our manufacturing methods and processes;
- our ability to identify patients with the diseases treated by our product candidates and to enroll these patients in our clinical trials;
- our expectations regarding the size of the patient populations, market acceptance and opportunity for and clinical utility of our product candidates, if approved for commercial use;
- our expectations regarding the scope of any approved indication for ADG20 or any other product candidate;
- our ability to successfully commercialize our product candidates;
- our ability to leverage our platform to identify and develop future product candidates;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements and our need for or ability to obtain additional funding before we can expect to generate any revenue from product sales and the period over which we expect the net proceeds from this offering, together with our existing cash and cash equivalents, to be sufficient to fund our operations;
- our expected use of proceeds from this offering;
- our competitive position and the development of and projections relating to our competitors or our industry; and
- business disruptions affecting our preclinical studies or the initiation, patient enrollment, development and operation of our clinical trials, including a public health crisis, such as the outbreak of COVID-19.

The foregoing list of forward-looking statements is not exhaustive. You should refer to the “Risk Factors” section of this prospectus for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Other sections of this prospectus may include additional factors that could harm our business and financial performance. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible



---

## Table of Contents

for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this prospectus will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks and other information we describe in the reports we will file from time to time with the SEC after the date of this prospectus.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, the events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

## MARKET AND INDUSTRY DATA

We are responsible for the disclosure contained in this prospectus. However, this prospectus contains industry, statistical and market data derived from our own internal estimates and research as well as from industry and general publications and research, surveys and studies conducted by third parties. The market and industry data used in this prospectus involve a number of assumptions and limitations, and any estimates underlying such market information and other factors, including those described in the section titled “Risk Factors,” could cause actual results to differ materially from those expressed in the third-party estimates and in our estimates.

## USE OF PROCEEDS

We estimate that the net proceeds to us from our issuance and sale of 18,200,000 shares of our common stock in this offering will be approximately \$283.9 million (or approximately \$327.1 million if the underwriters exercise in full their option to purchase up to 2,730,000 additional shares), based on the initial public offering price of \$17.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

As of March 31, 2021, we had cash and cash equivalents of \$91.2 million. In April 2021, we received gross proceeds of \$335.5 million from the issuance and sale of our Series C preferred stock. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents, as follows:

- approximately \$545.0 million to fund clinical development, manufacturing supply and initial commercialization costs for ADG20; and
- the remainder for working capital and other general corporate purposes, including development of additional programs in our pipeline.

We may also use a portion of the net proceeds from this offering to in-license, acquire or invest in complementary businesses, technologies, products or assets, although we have no current agreements, commitments or understandings to do so.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, which includes the proceeds from the issuance and sale of our Series C preferred stock in April 2021, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2023. Based on our current operational plans and assumptions, we expect the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to complete our ADG20 STAMP treatment trial and the post-exposure prophylaxis portion of the EVADE trial, make related regulatory filings and fund commercial launch. 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.

This expected use of the net proceeds from this offering and our existing cash and cash equivalents represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical studies or clinical trials we have ongoing or may commence in the future, any collaborations that we may enter into with third parties for our product candidates or strategic opportunities that become available to us, as well as any unforeseen cash needs.

Our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending their use, we plan to invest the net proceeds from this offering in short-term, interest bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States.

**DIVIDEND POLICY**

We have never declared or paid, and do not anticipate declaring or paying in the foreseeable future, any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business.

**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and our capitalization as of March 31, 2021:

- on an actual basis;
- on a pro forma basis to give effect to (i) our issuance and sale in April 2021 of 4,296,550 shares of our Series C preferred stock for gross proceeds of \$335.5 million, (ii) the automatic conversion of all outstanding shares of our preferred stock, including our Series C preferred stock, into an aggregate of 84,722,420 shares of common stock upon the closing of this offering and (iii) the filing and effectiveness of our amended and restated certificate of incorporation in connection with the completion of this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 18,200,000 shares of our common stock in this offering at the initial public offering price of \$17.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

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

	<b>As of March 31, 2021</b>		
	<b>Actual</b>	<b>Pro Forma</b>	<b>Pro Forma</b>
	<b>(in thousands, except share and per share data)</b>		
Cash and cash equivalents	<u>\$ 91,247</u>	<u>\$ 426,746</u>	<u>\$ 710,738</u>
Convertible preferred stock, \$0.0001 par value; 12,647,934 shares authorized, issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	<u>\$ 169,548</u>	<u>\$ —</u>	<u>\$ —</u>
<b>Stockholders’ equity (deficit):</b>			
Preferred stock, \$0.0001 par value; no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized and no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 28,193,240 shares issued and 5,593,240 shares outstanding, actual; 1,000,000,000 shares authorized, 112,915,660 shares issued and 90,315,660 shares outstanding, pro forma; 1,000,000,000 shares authorized, 131,115,660 shares issued and 108,515,660 shares outstanding, pro forma as adjusted	1	9	11
Treasury stock, at cost; 22,600,000 shares	(85)	(85)	(85)
Additional paid-in capital	741	505,780	789,720
Accumulated deficit	<u>(104,019)</u>	<u>(104,019)</u>	<u>(104,019)</u>
<b>Total stockholders’ equity (deficit)</b>	<u>(103,362)</u>	<u>401,685</u>	<u>685,627</u>
<b>Total capitalization</b>	<u>\$ 66,186</u>	<u>\$ 401,685</u>	<u>\$ 685,627</u>

## Table of Contents

The number of shares of our common stock to be outstanding after this offering is based on 90,315,660 shares of our common stock outstanding as of March 31, 2021, assuming the conversion of all outstanding shares of our preferred stock, including 4,296,550 shares of Series C preferred stock issued in April 2021, into an aggregate of 84,722,420 shares of common stock upon the closing of this offering, and excludes:

- 6,000 shares of our common stock issued subsequent to March 31, 2021;
- 5,366,070 shares of our common stock issuable upon the exercise of options outstanding as of March 31, 2021 under our 2020 Plan, at a weighted-average exercise price of \$2.49 per share (which does not include options to purchase an aggregate of 11,427,020 shares of our common stock, at a weighted-average exercise price of \$10.86 per share, that were granted subsequent to March 31, 2021);
- 11,860,995 shares of our common stock available for future issuance as of March 31, 2021 under the 2020 Plan, which such shares ceased to be available for issuance under the 2020 Plan at the time our 2021 Equity Incentive Plan, or the 2021 Plan, became effective and became available for issuance under the 2021 Plan;
- 6,434,485 additional shares of our common stock available for future issuance under our 2020 Plan, which was amended subsequent to March 31, 2021 to increase the shares available under the plan, which such shares ceased to be available for issuance under the 2020 Plan at the time our 2021 Plan became effective and became available for issuance under the 2021 Plan;
- 11,413,572 shares of our common stock that became available for future issuance under the 2021 Plan, which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan; and
- 1,342,773 shares of our common stock that became available for future issuance under our 2021 Employee Stock Purchase Plan, or the 2021 ESPP, which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 ESPP.

## DILUTION

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

Our historical net tangible book value (deficit) as of March 31, 2021 was \$(103.5) million, or \$(18.50) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and the carrying value of our preferred stock, which is not included within stockholders' equity (deficit). Historical net tangible book value (deficit) per share represents historical net tangible book value (deficit) divided by the 5,593,240 shares of our common stock outstanding as of March 31, 2021.

Our pro forma net tangible book value as of March 31, 2021 was \$401.6 million, or \$4.45 per share of common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) our issuance and sale in April 2021 of 4,296,550 shares of our Series C preferred stock for gross proceeds of \$335.5 million and (ii) the automatic conversion of all outstanding shares of our preferred stock, including our Series C preferred stock, into an aggregate of 84,722,420 shares of common stock upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the number of shares outstanding as of March 31, 2021, after giving effect to the pro forma adjustments described above.

After giving further effect to our issuance and sale of 18,200,000 shares of our common stock in this offering at the initial public offering price of \$17.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of March 31, 2021 would have been \$685.6 million, or \$6.32 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$1.87 to existing stockholders and immediate dilution of \$10.68 in pro forma as adjusted net tangible book value per share to new investors participating in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors. The following table illustrates this dilution on a per share basis:

Initial public offering price per share	\$17.00
Historical net tangible book value (deficit) per share as of March 31, 2021	\$(18.50)
Increase per share attributable to the pro forma adjustments described above	22.95
Pro forma net tangible book value per share as of March 31, 2021	4.45
Increase in pro forma as adjusted net tangible book value per share attributable to new investors participating in this offering	1.87
Pro forma as adjusted net tangible book value per share immediately after this offering	6.32
Dilution per share to new investors participating in this offering	<u>\$10.68</u>

If the underwriters exercise in full their option to purchase additional shares of common stock, our pro forma as adjusted net tangible book value per share after this offering would be \$6.55, representing an immediate increase in pro forma as adjusted net tangible book value per share of \$2.10 to existing stockholders and immediate dilution in pro forma as adjusted net tangible book value per share of \$10.45 to new investors participating in this offering, based on the initial public offering price of \$17.00 per share and after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The following table summarizes, as of March 31, 2021, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration and the average price per share (1) paid by existing stockholders and (2) to be paid by new investors participating in this offering at the



## Table of Contents

initial public offering price of \$17.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors participating in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percentage	Amount	Percentage	
Existing stockholders	90,315,660	83.2%	\$465,410,461	60.1%	\$ 5.15
Investors participating in this offering	18,200,000	16.8	309,400,000	39.9	\$ 17.00
Total	<u>108,515,660</u>	<u>100.0%</u>	<u>\$774,810,461</u>	<u>100.0%</u>	

The table assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters exercise in full their option to purchase additional shares of our common stock, the number of shares of our common stock held by existing stockholders would be reduced to 81.2% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in this offering would be increased to 18.8% of the total number of shares of our common stock outstanding after this offering.

The number of shares of our common stock to be outstanding after this offering is based on 90,315,660 shares of our common stock outstanding as of March 31, 2021, assuming the conversion of all outstanding shares of our preferred stock, including 4,296,550 shares of Series C preferred stock issued in April 2021, into an aggregate of 84,722,420 shares of common stock upon the closing of this offering, and excludes:

- 6,000 shares of our common stock issued subsequent to March 31, 2021;
- 5,366,070 shares of our common stock issuable upon the exercise of options outstanding as of March 31, 2021 under the 2020 Plan, at a weighted-average exercise price of \$2.49 per share (which does not include options to purchase an aggregate of 11,427,020 shares of our common stock, at a weighted-average exercise price of \$10.86 per share, that were granted subsequent to March 31, 2021);
- 11,860,995 shares of our common stock available for future issuance as of March 31, 2021 under the 2020 Plan, which such shares ceased to be available for issuance under the 2020 Plan at the time the 2021 Plan became effective and became available for issuance under the 2021 Plan;
- 6,434,485 additional shares of our common stock available for future issuance under our 2020 Plan, which was amended subsequent to March 31, 2021 to increase the shares available under the plan, which such shares ceased to be available for issuance under the 2020 Plan at the time our 2021 Plan became effective and became available for issuance under the 2021 Plan;
- 11,413,572 shares of our common stock that became available for future issuance under the 2021 Plan, which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 Plan; and
- 1,342,773 shares of our common stock that became available for future issuance under the 2021 ESPP, which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to this offering, as well as any automatic increases in the number of shares of common stock reserved for future issuance under the 2021 ESPP.

To the extent that outstanding stock options are exercised, new stock options or warrants are issued, or we issue additional shares of common stock, other equity securities or convertible debt securities in the future, there will be further dilution to our stockholders, including new investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we

---

[Table of Contents](#)

believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders, including new investors participating in this offering.

**SELECTED CONSOLIDATED FINANCIAL DATA**

You should read the following selected consolidated financial data together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this prospectus. We have derived the consolidated statement of operations data for the period from June 3, 2020 (inception) to December 31, 2020 and the consolidated balance sheet data as of December 31, 2020 from our audited consolidated financial statements appearing at the end of this prospectus. The consolidated statement of operations data for the three months ended March 31, 2021 and the consolidated balance sheet data as of March 31, 2021 have been derived from our unaudited consolidated financial statements appearing at the end of this prospectus and have been prepared on the same basis as the audited consolidated financial statements. In the opinion of management, the unaudited data reflect all adjustments, consisting only of normal recurring adjustments, necessary for a fair statement of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in any future period.

	Period from June 3, 2020 (Inception) to December 31, 2020	Three Months Ended March 31, 2021
	(in thousands, except per share data)	
<b>Consolidated Statement of Operations Data:</b>		
Operating expenses:		
Research and development <sup>(1)</sup>	\$ 21,992	\$ 34,032
Acquired in-process research and development <sup>(2)</sup>	40,125	1,000
Selling, general and administrative	3,210	3,677
Total operating expenses	65,327	38,709
Loss from operations	(65,327)	(38,709)
Other income:		
Interest income	8	9
Total other income	8	9
Net loss	\$ (65,319)	\$ (38,700)
Net loss per share attributable to common stockholders, basic and diluted <sup>(3)</sup>	\$ (18.10)	\$ —
Weighted-average common shares outstanding, basic and diluted <sup>(3)</sup>	3,608	—
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited) <sup>(4)</sup>	\$ (1.25)	\$ (0.61)
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited) <sup>(4)</sup>	52,167	63,240

- (1) Includes related-party amounts of \$0.6 million for the period from June 3, 2020 (inception) to December 31, 2020 and \$0.2 million for the three months ended March 31, 2021. See Note 6 to our consolidated financial statements appearing at the end of this prospectus.
- (2) Includes related-party amounts of \$39.9 million for the period from June 3, 2020 (inception) to December 31, 2020 and \$1.0 million for the three months ended March 31, 2021. See Note 6 to our consolidated financial statements appearing at the end of this prospectus.
- (3) See Note 13 to our consolidated financial statements appearing at the end of this prospectus for details on the calculation of basic and diluted net loss per share attributable to common stockholders.
- (4) Pro forma basic and diluted net loss per share attributable to common stockholders has been prepared to give effect to adjustments to our capital structure arising in connection with the completion of this offering and is calculated by dividing the pro forma net loss attributable to common stockholders by the pro forma

## [Table of Contents](#)

weighted-average common shares outstanding for the period. Pro forma net loss attributable to common stockholders is the same as the amount of net loss attributable to common stockholders for each period presented. Pro forma weighted-average common shares outstanding is computed by adjusting the weighted-average common shares outstanding to give pro forma effect to the automatic conversion of all shares of our preferred stock outstanding as of December 31, 2020 and March 31, 2021 into shares of common stock as if this offering had occurred on the later of June 3, 2020 (inception) or the issuance date of the preferred stock. Pro forma basic and diluted net loss per share attributable to common stockholders does not include the effect of the shares of Series C preferred stock we issued and sold in April 2021 and the shares expected to be sold in this offering.

	<u>As of</u> <u>December 31, 2020</u>	<u>As of</u> <u>March 31, 2021</u>
	(in thousands)	
<b>Consolidated Balance Sheet Data:</b>		
Cash and cash equivalents	\$ 114,988	\$ 91,247
Working capital <sup>(1)</sup>	104,310	66,197
Total assets	117,382	94,874
Convertible preferred stock	169,548	169,548
Total stockholders' deficit	(65,249)	(103,362)

(1) We define working capital as current assets less current liabilities.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the "Selected Consolidated Financial Data" section of this prospectus and our consolidated financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this prospectus, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

### Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential. We are developing our lead product candidate, ADG20, for the treatment and prevention 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 treatment and prevention options for years to come. We aim to address COVID-19 and future potential viral outbreaks by building a portfolio of antibodies with broadly neutralizing activity against multiple members of the coronavirus family or additional viruses with pandemic potential. Our portfolio of antibodies was discovered by Adimab, LLC, or Adimab, an industry leader in translating target hypotheses into therapeutically relevant antibodies with their proprietary platform, which has resulted in more than 385 antibody discovery programs.

ADG20 is designed to be a potent, long-acting and broadly neutralizing antibody for both the treatment and prevention of COVID-19 as either a single or combination agent. Unlike other antibody-based therapies specifically targeting SARS-CoV-2, ADG20 has demonstrated an ability in non-clinical studies to neutralize SARS-CoV-2, including variants of concern, as well as a broad range of SARS-like viruses with neutralization potency at IC<sub>50</sub> (half maximal inhibitory concentrations) of approximately 0.01 mcg/mL or less in live-virus cellular assays. We believe this demonstrated *in vitro* neutralization activity will translate into the ability to conveniently deliver ADG20 as a single intramuscular, or IM, injection. We believe these and other attributes of ADG20 differentiate it from other antibodies that are either available under Emergency Use Authorization, or EUA, or in development to address COVID-19. We have completed enrollment in our first-in-human Phase 1 clinical trial of ADG20. Interim data demonstrated that ADG20 was well tolerated and displayed a pharmacokinetic profile consistent with an extended half-life monoclonal antibody, or mAb. Serum virus neutralizing antibody titers measured the day following administration of ADG20 were similar to or exceeded peak serum neutralizing antibody titers generated after two doses of mRNA or adenovirus-based COVID-19 vaccines. Based on these data, we are conducting two separate Phase 2/3 clinical trials: our STAMP trial to evaluate ADG20 for the treatment of COVID-19 and our EVADE trial to evaluate ADG20 for the prevention of COVID-19. Additionally, our portfolio includes multiple broadly neutralizing antibodies, including ADG10, for potential use with ADG20 as a combination therapy for the treatment and prevention of COVID-19 and future coronavirus outbreaks.

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.

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

## Table of Contents

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 of our product candidates. Since our inception, we have financed our operations with proceeds from sales of our preferred stock. Through March 31, 2021, we had received net proceeds of \$129.5 million from the sales of our preferred stock. In addition, in April 2021, we received gross proceeds of \$335.5 million from sales of our Series C preferred stock. To date, we have not generated any revenue from any sources, including product sales. In February 2021, we advanced ADG20 into a Phase 1 clinical trial. 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 \$65.3 million for the period from June 3, 2020 (inception) to December 31, 2020 and of \$38.7 million for the three months ended March 31, 2021. As of March 31, 2021, we had an accumulated deficit of \$104.0 million. We expect to continue to incur significant expenses and recognize substantial 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 significantly in connection with our ongoing activities, as we:

- continue to conduct our ongoing clinical trials of ADG20, including advancement into 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 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;
- develop, establish and validate our commercial-scale cGMP manufacturing process;
- 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.

## Table of Contents

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, 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.

We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operating expenses and capital expenditure requirements into the first quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “—Liquidity and Capital Resources.”

Without giving effect to the anticipated net proceeds from this offering, as of May 21, 2021, we expect that our existing cash and cash equivalents, including the \$335.5 million of gross proceeds we received from sales of our Series C preferred stock in April 2021, will be sufficient to fund our operating expenses and capital expenditure requirements through March 31, 2022. Beyond that point, we will need to raise additional capital to finance our operations, which cannot be assured. We concluded as of May 21, 2021, the issuance date of our consolidated financial statements for the period from June 3, 2020 (inception) to December 31, 2020 and of our interim consolidated financial statements for the three months ended March 31, 2021, that this circumstance raised substantial doubt about our ability to continue as a going concern within one year of the issuance date of those consolidated financial statements. See Note 1 to our consolidated financial statements appearing at the end of this prospectus for additional information on our assessment.

Similarly, in its report on our consolidated financial statements for the period from June 3, 2020 (inception) to December 31, 2020, our independent registered public accounting firm included an explanatory paragraph stating that our recurring losses from operations since inception, expectation of generating operating losses in the foreseeable future and need for additional capital to finance our future operations raise substantial doubt about our ability to continue as a going concern.

### ***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 ADG20 for the treatment and prevention of COVID-19. The severity of the COVID-19 pandemic and the



## [Table of Contents](#)

continued emergence of variants of concern, the availability, administration and acceptance of vaccines and monoclonal antibodies 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, such as travel, 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 the outbreak and its impact on our clinical trial design and enrollment, trial sites, CROs, 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 not experienced significant delays or disruptions in our development activities as a result of the COVID-19 pandemic but may in the future as the outbreak progresses and some of our CROs, CDMOs and other service providers 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.

#### ***Operating Expenses***

##### ***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;

## Table of Contents

- 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 ADG20. 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 ADG20 through clinical development on a global basis, pursue regulatory approval of ADG20, 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;

## Table of Contents

- the prevalence and severity of adverse events experienced with ADG20 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. In addition, we may never succeed in obtaining regulatory approval or EUA for any of our product candidates.

### ***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 and royalties 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 and royalty 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 significantly 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

## Table of Contents

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 March 31, 2021, we have operated as a virtual company. Therefore, we do not incur material operating expenses for the rent, maintenance and insurance of facilities or for depreciation of fixed assets. We plan to enter into a lease for office space in the near term, which would increase our operating costs.

### ***Interest Income***

Interest income consists of interest earned from our cash and cash equivalents. We expect our interest income will increase slightly as we invest the cash received from our sales of Series C preferred stock in April 2021 and the net proceeds from this offering.

### ***Income Taxes***

Since our inception, we have not recorded any income tax 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.

As of December 31, 2020, we had U.S. federal NOL carryforwards of \$24.4 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, 2020, we had state NOL carryforwards of \$3.7 million, which may be available to reduce future taxable income, of which \$0.3 million have an indefinite carryforward period while the remaining \$3.4 million begin to expire in 2040. As of December 31, 2020, we also had U.S. federal and state research and development tax credit carryforwards of \$0.1 million and \$16,000, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2040 and 2035, respectively. We have recorded a full valuation allowance against our net deferred tax assets at each balance sheet date.

## **Results of Operations**

The following table summarizes our results of operations for the period from June 3, 2020 (inception) to December 31, 2020 and for the three months ended March 31, 2021:

	Period from June 3, 2020 (Inception) to December 31, 2020	Three Months Ended March 31, 2021
	(in thousands)	
Operating expenses:		
Research and development	\$ 21,992	\$ 34,032
Acquired in-process research and development	40,125	1,000
Selling, general and administrative	3,210	3,677
Total operating expenses	<u>65,327</u>	<u>38,709</u>
Loss from operations	<u>(65,327)</u>	<u>(38,709)</u>
Other income:		
Interest income	8	9
Total other income	<u>8</u>	<u>9</u>
Net loss	<u>\$ (65,319)</u>	<u>\$ (38,700)</u>

## [Table of Contents](#)

The description of material changes from period to period required by Item 303 of Regulation S-K cannot be presented as no company-related activities were performed by any party before our company was formed on June 3, 2020 and there are no comparative earlier periods for purposes of this analysis. Accordingly, the following discussion presents the components of our expenses for the periods presented.

### *Research and Development Expenses*

	Period from June 3, 2020 (Inception) to December 31, 2020	Three Months Ended March 31, 2021
	(in thousands)	
Direct, external research and development expenses by program:		
ADG20	\$ 18,523	\$ 30,652
Unallocated research and development expenses:		
Personnel related (including stock-based compensation)	1,743	2,260
External discovery-related costs and other	1,726	1,120
Total research and development expenses	<u>\$ 21,992</u>	<u>\$ 34,032</u>

Research and development expenses were \$22.0 million for the period from June 3, 2020 (inception) to December 31, 2020 and consisted primarily of the following:

- \$14.8 million of contract manufacturing expenses related to the production of materials for use in our preclinical studies and clinical trials for the ADG20 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 ADG20 program;
- \$1.0 million of other external research and development costs associated with the ADG20 program, including with respect to consulting services, insurance costs and software expenditures;
- \$1.3 million of non-clinical studies expenses associated with the ADG20 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 ADG20 program were incurred in connection with our first-in-human Phase 1 clinical trial to evaluate ADG20 and our Phase 2/3 STAMP trial of ADG20 for the treatment of COVID-19.

Research and development expenses were \$34.0 million for the three months ended March 31, 2021 and consisted primarily of the following:

- \$20.4 million of contract manufacturing expenses related to the production of materials for use in our preclinical studies and clinical trials for the ADG20 program, procured primarily from WuXi, our sole-source supplier of drug substance;
- \$7.5 million of clinical trial expenses related to start-up activities for our clinical trials for the ADG20 program, including site initiation and patient enrollment;
- \$1.8 million of other external research and development costs associated with the ADG20 program, including with respect to consulting services, insurance costs and software expenditures;
- \$0.9 million of non-clinical studies expenses associated with the ADG20 program;

## Table of Contents

- \$2.3 million of personnel-related costs, including salaries, bonuses and other compensation-related costs, including stock-based compensation of \$0.3 million; and
- \$1.1 million of external discovery-related and other costs.

The contract manufacturing, clinical and other external research and development costs for our ADG20 program were incurred in connection with our first-in-human Phase 1 clinical trial to evaluate ADG20, which was initiated in February 2021, and our Phase 2/3 STAMP trial of ADG20 for the treatment of COVID-19, which was initiated in March 2021.

### ***Acquired In-Process Research and Development Expenses***

Acquired IPR&D expenses of \$40.1 million for the period from June 3, 2020 (inception) to 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. We expensed the cost of the IPR&D assets acquired because they had no alternative future use as of the acquisition date. The \$39.9 million of costs to acquire the IPR&D assets was determined as a result of our allocation of the \$40.0 million aggregate fair value of the 5,000,000 shares of the Series A preferred stock that we issued to Adimab on the acquisition date in exchange for (i) the IPR&D assets acquired from Adimab and (ii) 4,250,000 shares of our common stock that we repurchased from Adimab on that same date. We allocated the \$40.0 million fair value of the 5,000,000 shares of Series A preferred to the IPR&D assets and to the repurchased common stock based on their relative fair values on the acquisition date. We 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 our Series A preferred stock financing, which closed on the same date as the date on which we acquired the intellectual property rights and license from Adimab.

Acquired IPR&D expenses of \$1.0 million for the three months ended March 31, 2021 consisted of the cost we incurred in the period under the Adimab Assignment Agreement for a milestone payment that became due to Adimab in February 2021 upon the dosing of the first patient in a Phase 1 clinical trial evaluating ADG20. The amount of this contingent payment was recognized as an IPR&D expense based on the nature of the associated assets acquired from Adimab on the date of the milestone achievement.

### ***Selling, General and Administrative Expenses***

	<b>Period from June 3, 2020 (Inception) to December 31, 2020</b>	<b>Three Months Ended March 31, 2021</b>
	(in thousands)	
Personnel related (including stock-based compensation)	\$ 1,239	\$ 1,494
Professional and consultant fees	1,849	1,969
Other	122	214
Total selling, general and administrative expenses	<u>\$ 3,210</u>	<u>\$ 3,677</u>

Selling, general and administrative expenses were \$3.2 million for the period from June 3, 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;

## Table of Contents

- \$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.

Selling, general and administrative expenses were \$3.7 million for the three months ended March 31, 2021 and consisted primarily of the following:

- \$1.5 million of personnel-related costs, including salaries, bonuses and other compensation-related costs, including stock-based compensation of \$0.3 million;
- \$1.1 million of professional service fees, including corporate legal costs as well as costs related to intellectual property, legal and compliance costs;
- \$0.9 million of market research costs relating to developing our potential commercialization plans and consumer brand-related matters; and
- \$0.2 million related to non-capital software and hardware and other office-related expenses.

### **Interest Income**

Interest income for the period from June 3, 2020 (inception) to December 31, 2020 and for the three months ended March 31, 2021 was \$8,000 and \$9,000, respectively, consisting of interest earned on our cash and cash equivalents.

## **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 significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. To date, we have funded our operations with proceeds from sales of our preferred stock. Through March 31, 2021, we had received net proceeds of \$129.5 million from sales of our preferred stock. As of March 31, 2021, we had cash and cash equivalents of \$91.2 million. In addition, in April 2021, we received gross proceeds of \$335.5 million from sales of our Series C preferred stock.

### **Cash Flows**

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

	<b>Period from June 3, 2020 (Inception) to December 31, 2020</b>	<b>Three Months Ended March 31, 2021</b>
	(in thousands)	
Net cash used in operating activities	\$ (14,571)	\$ (23,741)
Net cash provided by financing activities	129,559	—
Net increase in cash and cash equivalents	<u>\$ 114,988</u>	<u>\$ (23,741)</u>

### **Operating Activities**

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

## Table of Contents

\$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.

During the three months ended March 31, 2021, operating activities used \$23.7 million of cash, primarily resulting from our net loss of \$38.7 million, partially offset by non-cash charges of \$0.6 million and net cash provided by changes in our operating assets and liabilities of \$14.4 million. Net cash provided by changes in our operating assets and liabilities for the three months ended March 31, 2021 consisted primarily of a \$12.4 million increase in accrued expenses and a \$3.2 million increase in accounts payable, both partially offset by a \$1.2 million increase in prepaid expenses and other current assets. The increases in accounts payable, accrued expenses and prepaid expenses were primarily due to increased external costs associated with our research and development activities, including clinical trials and manufacturing.

### *Investing Activities*

We had no cash used in or provided by investing activities for the period from June 3, 2020 (inception) to December 31, 2020 or for the three months ended March 31, 2021.

### *Financing Activities*

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.

We had no cash used in or provided by financing activities for the three months ended March 31, 2021.

### *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 AGD20 and our other product candidates;
- the scope, progress, results and costs of non-clinical studies, preclinical development, laboratory testing and clinical trials for ADG20 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 ADG20 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;



## Table of Contents

- 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 the net proceeds from this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements into the first quarter of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

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,

## [Table of Contents](#)

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, 2020 (in thousands):

	Payments Due by Period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
Manufacturing agreement <sup>(1)</sup>	\$142,865	\$21,799	\$121,066	\$ —	\$ —
License agreement	150	150	—	—	—
Total <sup>(2)</sup>	<u>\$143,015</u>	<u>\$21,949</u>	<u>\$121,066</u>	<u>\$ —</u>	<u>\$ —</u>

- (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, 2020, based on the expected due dates for such purchases.
- (2) Through December 31, 2020, we have operated as a virtual company. Therefore, we do not maintain a corporate headquarters or have material leasing arrangements.

We have a manufacturing agreement with WuXi, which outlines the terms and conditions under which it will manufacture ADG20 drug substance for commercial use. Our requirements for manufacture of ADG20 for the years ending December 31, 2021 and 2022, the payments for which will extend into 2023, are governed by a binding, forecasted schedule and are presented in the preceding table.

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 March 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.

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 clinical trial evaluating ADG20, 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 clinical trial evaluating ADG20 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. The next potential milestone payment that we may be obligated to make is a \$4.0 million milestone payment for the first dosing of the first subject in the first Phase 3 clinical trial of a product licensed under the agreement. 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 “Business—Licensing, Collaborations and Partnerships—Assignment and License Agreement with Adimab” and “Certain Relationships and Related Party Transactions” appearing elsewhere in this prospectus.

## **Table of Contents**

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, 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 "Business—Licensing, Collaborations and Partnerships—Collaboration Agreement with Adimab" and "Certain Relationships and Related Party Transactions" appearing elsewhere in this prospectus.

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 prospectus, 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

## Table of Contents

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. 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.

### ***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

## Table of Contents

option-pricing model. We have issued awards with only service-based vesting conditions. 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. We have issued awards with only service-based vesting conditions through March 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.

### ***Determination of Fair Value of Common Stock***

As there has been no public market for our common stock prior to this offering, the estimated fair value of our common stock underlying our stock-based awards has been 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.

These third-party valuations were performed at various dates, which resulted in valuations of our common stock of \$0.00 per share as of June 19, 2020, \$0.78 per share as of July 9, 2020, \$4.61 per share as of October 31, 2020, \$8.36 as of March 15, 2021, \$10.14 as of May 1, 2021 and \$12.81 as of June 23, 2021. 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;

## Table of Contents

- 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.

Once a public trading market for our common stock has been established in connection with the completion of this offering, it will no longer be necessary for our board of directors to estimate the fair value of our common stock in connection with our accounting for granted stock options and other such awards we may grant, as the fair value of our common stock will be based on the quoted market price of our common stock.

### **Option Grants**

The following table summarizes by grant date the number of shares subject to options granted since June 3, 2020 (inception), the per share exercise price of the options, the per share fair value of our common stock on each grant date and the per share estimated fair value of the options:

<u>Grant Date</u>	<u>Number of Shares Subject to Options Granted</u>	<u>Per Share Exercise Price of Options</u>	<u>Per Share Fair Value of Common Stock on Grant Date</u>	<u>Per Share Estimated Fair Value of Options</u>
June 19, 2020	6,943,240	\$0.01	\$0.01	\$0.01
September 28, 2020	2,968,070	\$0.78	\$1.00 <sup>(1)</sup>	\$0.68
January 13, 2021	2,513,000	\$4.61	\$4.61	\$2.95
April 13, 2021	1,198,750	\$8.36	\$8.36	\$5.50
May 7, 2021	6,341,740	\$ 10.14	\$ 10.14	\$6.68
June 30, 2021	2,025,070	\$ 12.81	\$ 12.81	\$8.23
July 4, 2021	1,861,460	\$ 12.81	\$ 12.81	\$8.26

- (1) At the time of the option grant on September 28, 2020, our board of directors determined that the fair value of our common stock of \$0.78 per share reasonably reflected the fair value of our common stock as of the grant date, based on a contemporaneous valuation obtained. However, as described below, the fair value of our common stock at the date of this grant was adjusted in connection with a retrospective fair value assessment for accounting purposes.

In the course of preparing for this offering, in April 2021, we performed a retrospective fair value assessment and concluded that the fair value of our common stock underlying stock options that we granted on September 28, 2020 was \$1.00 per share for accounting purposes. This reassessed value was based, in part, upon a third-party valuation of our common stock prepared on a retrospective basis as of September 28, 2020. The third-party retrospective valuation was prepared using an OPM, which used a market approach to determine our

## [Table of Contents](#)

enterprise value. We applied the fair value of our common stock from our retrospective fair value assessment to determine the fair value of these awards and calculate stock-based compensation expense for accounting purposes.

### **Off-Balance Sheet Arrangements**

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

### **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 prospectus.

### **Internal Control over Financial Reporting**

We identified a material weakness in our internal control over financial reporting that existed as of March 31, 2021. See “Risk Factors—We have identified a material weakness in our internal control over financial reporting. If we are unable to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business.”

### **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.

### **Quantitative and Qualitative Disclosures About Market Risk**

As of December 31, 2020, we had cash and cash equivalents of \$115.0 million, which consisted of cash and a money market fund. As of March 31, 2021, we had cash and cash equivalents of \$91.2 million, which consisted of cash and a money market fund. Interest income is sensitive to changes in the general level of interest rates; however, due to the nature of these investments, an immediate 10% change in interest rates would not have a material impact on the fair value of our investment portfolio. As of December 31, 2020 and March 31, 2021, we had no debt outstanding. Therefore, we are not exposed to interest rate risk with respect to debt.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. Our operations may be subject to inflation in the future.



## BUSINESS

### Overview

We are a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential. We are developing our lead product candidate, ADG20, for the treatment and prevention 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 treatment and prevention options for years to come. We aim to address COVID-19 and future potential viral outbreaks by building a portfolio of antibodies with broadly neutralizing activity against multiple members of the coronavirus family or additional viruses with pandemic potential. Our portfolio of antibodies was discovered by Adimab, LLC, or Adimab, an industry leader in translating target hypotheses into therapeutically relevant antibodies with their proprietary platform, which has resulted in more than 385 antibody discovery programs, over 40 of which have advanced into clinical trials.

ADG20 is designed to be a potent, long-acting and broadly neutralizing antibody for both the treatment and prevention of COVID-19 as either a single or combination agent. Unlike other antibody-based therapies specifically targeting SARS-CoV-2, ADG20 has demonstrated in non-clinical studies an ability to neutralize SARS-CoV-2, including variants of concern, as well as a broad range of SARS-like viruses with neutralization potency at IC<sub>50</sub> (half maximal inhibitory concentrations) of approximately 0.01 mcg/mL or less in live-virus cellular assays. We believe this demonstrated *in vitro* neutralization activity will translate into the ability to conveniently deliver ADG20 as a single intramuscular, or IM, injection. We believe these and other attributes of ADG20 differentiate it from other antibodies that are either available under Emergency Use Authorization, or EUA, or in development to address COVID-19. We have completed enrollment in our first-in-human Phase 1 clinical trial of ADG20. Interim data demonstrated that ADG20 was well tolerated and displayed a pharmacokinetic profile consistent with an extended half-life monoclonal antibody, or mAb. Serum virus neutralizing antibody titers measured the day following administration of ADG20 were similar to or exceeded peak serum neutralizing antibody titers generated after two doses of mRNA or adenovirus-based COVID-19 vaccines. Based on these data, we are conducting two separate Phase 2/3 clinical trials: our STAMP trial to evaluate ADG20 for the treatment of COVID-19 and our EVADE trial to evaluate ADG20 for the prevention of COVID-19. Additionally, our portfolio includes multiple broadly neutralizing antibodies, including ADG10, for potential use with ADG20 as a combination therapy for the treatment and prevention of COVID-19 and future coronavirus outbreaks.

Over the past 20 years, three pathogenic novel coronaviruses have spilled over into the human population from animal reservoirs to cause outbreaks of deadly pneumonia, including COVID-19, severe acute respiratory syndrome, or SARS, and Middle East respiratory syndrome, or MERS. Most recently, SARS-CoV-2 has given rise to a global pandemic that swept rapidly throughout the world in 2020. Of significant current concern is the emergence of a number of SARS-CoV-2 variants with increased transmissibility 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) uneven global rollout of vaccinations; (2) ongoing vaccine hesitancy; (3) unknown duration of immunity and efficacy against current and future viral variants conferred by currently available vaccines; (4) uncertain impact of vaccines on transmission; and (5) variable implementation of virus mitigation behaviors, such as wearing masks and social distancing. As a result, our epidemiological modeling has suggested that as much as 50% of the global population may be susceptible to SARS-CoV-2 infection within three years. 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 SARS-like viruses that are capable of infecting humans.

Our vision is to discover, develop and commercialize antibody-based solutions not only for the current COVID-19 pandemic, but also to address future potential coronavirus outbreaks. To enable this vision, our



## [Table of Contents](#)

discovery efforts are focused on broadly neutralizing antibodies that target conserved epitopes across multiple members of the coronavirus family. We optimize our candidate molecules to improve breadth, potency, half-life and developability. Key elements that differentiate our approach include: (1) recognition of the importance of broadly neutralizing antibodies; (2) industry-leading B-cell mining, protein engineering and developability screening capabilities through our partnership with Adimab; and (3) development of antibodies with reduced risk of clinical resistance. We believe that a mAb therapy that provides potent and broad neutralizing activity, convenient outpatient administration and both rapid and durable protection will have the potential to address the limitations of currently available treatment and prevention options for COVID-19 as well as future diseases that may arise from SARS-like viruses with pandemic potential.

Our founding scientists designed and engineered ADG20 with the goal of creating a highly active and broad mAb-based therapeutic candidate for both the treatment and prevention of COVID-19. They focused on isolating an antibody capable of broadly neutralizing the entire viral class of SARS-like viruses, known as sarbecoviruses, as opposed to only neutralizing SARS-CoV-2.

We have completed enrollment in our first-in-human Phase 1 clinical trial in healthy volunteers. Interim data demonstrated that ADG20 was well tolerated and displayed a pharmacokinetic profile consistent with an extended half-life mAb. In addition, the serum virus neutralizing antibody titers measured the day following administration of ADG20 were similar to or exceeded peak serum neutralizing antibody titers generated after two doses of mRNA or adenovirus-based COVID-19 vaccines. For the treatment of mild to moderate COVID-19 in patients at high risk of disease progression, we are conducting our STAMP trial, a combined Phase 2/3 global clinical trial designed to provide a path to applying for EUA and/or filing a BLA for marketing approval in 2022, and commercial launch thereafter, if ADG20 is approved. We may not meet our time frames for submission for an EUA or a BLA, and if we do meet such timelines, there is no guarantee the FDA would approve our submission, or on the time frame we have indicated. For the prevention of COVID-19, we are conducting our EVADE trial, a combined Phase 2/3 clinical trial in both post-exposure and pre-exposure populations. If these clinical trials are successful, we believe ADG20 has the potential to be approved for both the treatment and prevention of COVID-19 in the United States, potentially preceded by an EUA for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. Importantly, given the global impact of COVID-19, we also plan to seek approvals outside the United States as well. In addition, we are developing a clinical plan to support the use of ADG20 in the pediatric population for both the treatment and prevention of COVID-19.

We are also evaluating additional broadly neutralizing antibodies, such as ADG10, for potential use in combination with ADG20 for COVID-19. We believe the incorporation of a second broadly neutralizing antibody that targets a distinct viral epitope from the epitope targeted by ADG20 will ensure long-lasting product activity against COVID-19 as new variants of SARS-CoV-2 emerge, as well as against future potential outbreaks of disease that may arise from additional SARS-like viruses with pandemic potential. In addition, we plan to leverage the robust antibody discovery and development capabilities that have enabled our expedited advancement of ADG20 into clinical trials to develop therapeutic or preventative options for other respiratory viral infections, such as additional coronaviruses and seasonal and pandemic 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.

### **Our History and Team**

We were founded in June 2020 to develop a portfolio of anti-coronavirus antibodies discovered by Adimab for both the treatment and prevention of COVID-19 and future coronavirus outbreaks. Our founding scientists discovered ADG20, our lead product candidate, while working at Adimab, an industry leader in translating target hypotheses into therapeutically relevant antibodies. The Adimab platform has been used in more than 385 antibody discovery and optimization programs, more than 40 of which have advanced into clinical trials, including five programs in pivotal clinical trials. In order to maximize ADG20's potential and to ensure its development and commercialization with appropriate infectious disease resources and development expertise, we

## [Table of Contents](#)

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 mAbs. Many of our team members have held senior positions at companies such as Cubist Pharmaceuticals, Inc., Vir Biotechnology Inc., Adimab, Biogen and Ironwood Pharmaceuticals, among others.

Since our inception, we have raised approximately \$470 million of capital from leading institutional healthcare investors and our partners. 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.

### **Our Strategy**

Our goal is to develop and commercialize differentiated antibody-based solutions with broadly neutralizing activity for the treatment and prevention of diseases caused by SARS-CoV-2, its variants and additional SARS-like viruses with pandemic potential. In order to achieve this goal, our strategy involves executing on the following key elements:

- **Leverage our team’s collective expertise in development, manufacturing and commercialization to efficiently bring ADG20 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 therapies. Based on our team’s successful track record, collectively, we believe we will be able to execute on the clinical, regulatory, manufacturing and commercialization plan for ADG20, as well as any future programs, in an efficient manner.
- **Complete development and obtain global approval for our lead product candidate, ADG20, for both the treatment and prevention of COVID-19.** Our clinical development plan for ADG20 includes two global clinical trials to demonstrate the efficacy and safety of ADG20 for treatment and prevention of COVID-19, respectively. We have completed enrollment in our first-in-human Phase 1 clinical trial in healthy volunteers. Interim data demonstrated that ADG20 was well tolerated and displayed a pharmacokinetic profile consistent with an extended half-life mAb. In addition, the serum virus neutralizing antibody titers measured the day following administration of ADG20 were similar to or exceeded peak serum neutralizing antibody titers generated after two doses of mRNA or adenovirus-based COVID-19 vaccines. For the treatment of mild to moderate COVID-19 in patients at high risk of disease progression, we are conducting our Phase 2/3 STAMP trial, which is designed to provide a path to applying for emergency use authorization and/or filing a BLA for marketing approval in 2022, and commercial launch thereafter, if ADG20 is approved. We may not meet our time frames for submission for an EUA or a BLA, and if we do meet such timelines, there is no guarantee the FDA would approve our submission, or on the time frame we have indicated. This clinical trial includes an interim analysis for efficacy, which has the potential to support an EUA. The clinical data from the interim analysis will be further supplemented with nonclinical virological data demonstrating broad neutralizing activity against a comprehensive panel of known SARS-CoV-2 variants, including variants that are partially or fully resistant to certain currently available mAb therapies and vaccines. Similarly, we are conducting our Phase 2/3 global clinical trial, EVADE, to evaluate ADG20 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. If our STAMP and EVADE trials are successful, we believe ADG20 has the potential to be approved for both the treatment and prevention of COVID-19 in the United States, potentially preceded by an EUA for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. Importantly, given the global impact of COVID-19, we also plan to seek approvals outside the United States.

## [Table of Contents](#)

- **Successfully commercialize ADG20, if approved.** We believe ADG20 will have several attractive clinical and commercial attributes, including (1) potent and broad neutralizing activity across sarbecoviruses, including against SARS-CoV-2 and known, circulating variants of concern; (2) rapid onset of protection; (3) differentiated durability; (4) convenient, single-dose IM injection for use in the outpatient setting; (5) ability to both complement and supplement currently available COVID-19 vaccines, including for immunocompromised individuals; (6) high titer, high yield manufacturing process; (7) standard refrigeration requirements to facilitate worldwide distribution and storage; and (8) long shelf life to enable stockpiling. Our plan for the commercialization of ADG20 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 and Europe, where we believe a focused commercial infrastructure will be able to successfully commercialize ADG20. In other markets, such as Latin America, Asia-Pacific, including China, and Middle Eastern and African countries, we intend to commercialize ADG20 through partnerships. For example, in July 2021, we entered into a license agreement with Biocon to combat the ongoing COVID-19 crisis in southern Asia.
- **Continue to secure additional manufacturing capacity with trusted CDMO partners to enable a worldwide commercial launch.** Due to ongoing worldwide manufacturing capacity constraints, we have identified and secured the necessary manufacturing capabilities and capacity to enable the development and commercialization of ADG20. In partnership with WuXi Biologics (Hong Kong) Limited, or WuXi, we have developed a high titer, high yield manufacturing process and a formulation that enables IM delivery and have manufactured all the required doses for our STAMP and EVADE clinical trials. We have also selected WuXi as our initial commercial manufacturing partner and believe we have secured sufficient capacity for our initial commercial launch, if ADG20 is approved. We are continuing to evaluate access to additional capacity at both WuXi and other CDMOs to ensure we can meet expected long-term commercial demand.
- **Develop additional antibodies for use in potential combination with ADG20 to address future potential variants of SARS-CoV-2 and other sarbecovirus outbreaks.** The current COVID-19 pandemic has been exacerbated by the global emergence and spread of SARS-CoV-2 variants with varying levels of resistance to existing therapies, highlighting the need for proactive planning to allow for a rapid and effective response against future coronavirus outbreaks. We are building a portfolio of broadly neutralizing antibodies that target viral epitopes distinct from that targeted by ADG20. We believe combinations of these antibodies, including with ADG20, have the potential to further enhance the breadth and effectiveness of our products.
- **Leverage relationships with Adimab and academic institutions to discover additional antibody-based solutions to address coronaviruses and influenza infections.** Our ongoing relationship with Adimab provides us with access to Adimab's unique B-cell mining and protein engineering capabilities. We believe this relationship will allow us to further expand our portfolio with additional uniquely differentiated antibodies for coronaviruses as well as influenza. In addition, we collaborate with academic institutions for the discovery of vaccine immunogens that elicit broadly protective immune responses against influenza and coronaviruses.

## **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. 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 major antigen target for the host immune response, and neutralizing antibodies to this protein are associated with protection from infection and disease. For this reason, S protein is the primary target for currently available vaccines and therapeutic mAbs.

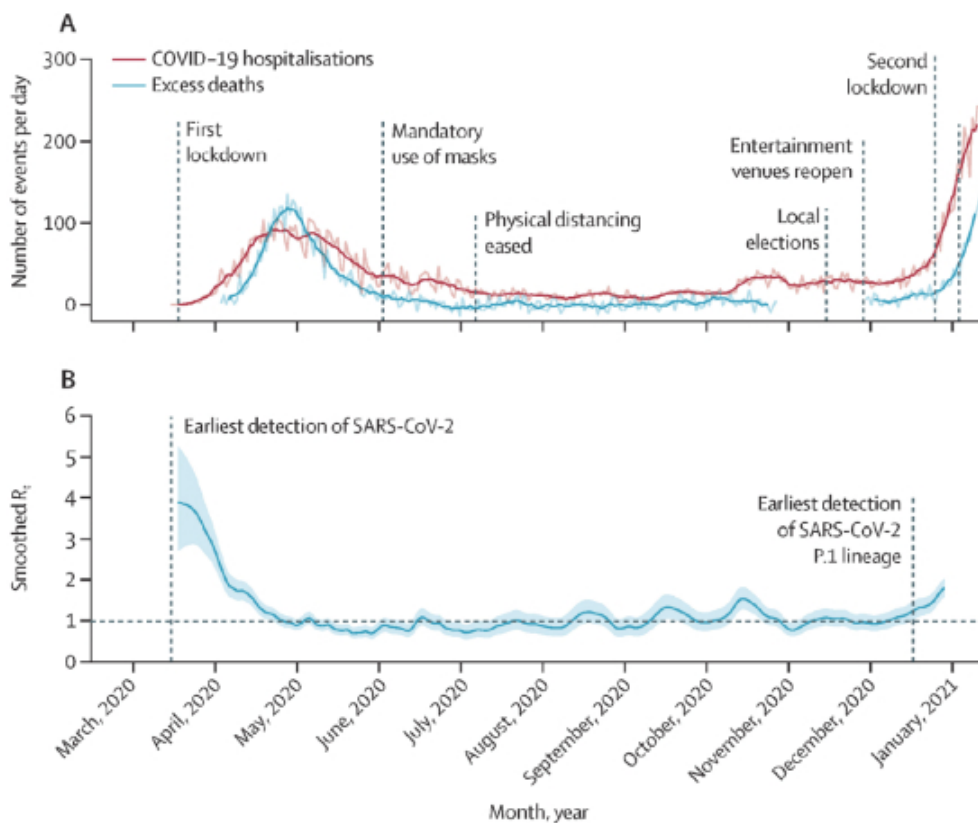
COVID-19 remains a significant global health crisis and case numbers continue to rise. According to estimates as of May 20, 2021 from the Johns Hopkins University, there have been approximately 165 million cases of laboratory-confirmed COVID-19 and 3.4 million COVID-19-related deaths worldwide, with over 33 million laboratory-confirmed cases of COVID-19 and more than 587,000 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 and/or the ability to evade neutralizing antibodies. These variants include Alpha (B.1.1.7), which was first detected in the United Kingdom; Beta (B.1.351), which was first detected in South Africa; Gamma (P.1), which was first detected in Brazil and shares phenotypic characteristics with B.1.351, and Delta (B.1.617.2), which was first detected in India. Since their initial detection, all of these variants have spread rapidly worldwide, with confirmed cases in the United States, Canada and several European countries, indicating that these variants may be more contagious than the original SARS-CoV-2. As of the two weeks ended July 17, 2021, the Delta (B.1.617.2) variant accounted for approximately 80% of all new COVID-19 cases in the United States and was rapidly increasing. Emergence of the Delta variant in the United States has been accompanied by an increase in COVID-19 cases and hospitalizations. In addition to these well-known variants, additional novel variants have emerged in the United States, including Epsilon (B.1.429/427) and Iota (B.1.526), which were first detected in California and New York, respectively.

## Table of Contents

A subset of these variants, notably Beta (B.1.351), Gamma (P.1) and Delta (B.1.617.2), have caused reinfections and breakthrough infections in individuals with pre-existing antibody responses due to prior infection or vaccination, indicating that pre-existing antibodies do not necessarily fully protect against these variants. For example, in the Brazilian city of Manaus, despite a high rate of prior infection as indicated by an estimated seroprevalence of 76% in October 2020, a second wave of COVID-19 cases began in November 2020, which resulted in a significant increase in hospitalizations and deaths. As illustrated in the timeline below, this second COVID-19 wave closely coincided with the emergence of the Gamma (P.1) variant in the city. More recently, we have seen the global emergence and spread of the Delta variant with increases in case loads and hospitalizations, even in countries, such as the United Kingdom and the United States, with relatively high vaccination rates.

### Infection Rates in Manaus, Brazil Demonstrate a Surge in Infections Following the Emergence of the P.1 Variant



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) uneven global rollout of vaccinations; (2) ongoing vaccine hesitancy; (3) unknown duration of immunity and efficacy against current and future viral variants conferred by currently available vaccines; (4) uncertain impact of vaccines on transmission; and (5) variable implementation of virus mitigation behaviors, such as wearing masks and social distancing.

### Current Approaches for Treatment and Prevention 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 authorized for the prevention of COVID-19 under public health emergency guidelines 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 Vaxzevria/Covishield, or AZD1222, and Janssen's JNJ-78436735. While available COVID-19 vaccines have demonstrated meaningful efficacy in preventing COVID-19, we believe additional solutions for the prevention of COVID-19 are required given considerable uncertainty related to multiple factors, including:

- ***Efficacy against viral variants.*** While COVID-19 vaccines have demonstrated meaningful efficacy in preventing infection by the original strain of COVID-19, emerging evidence shows lower levels of protection against certain variants. A recent Israeli study demonstrated that a disproportionate number of breakthrough infections in Pfizer/BioNTech vaccine recipients are caused by the Beta (B.1.351) variant, and more recent real-world use data from Israel suggests lower vaccine effectiveness against the Delta variant. Clinical trials have also shown reduced efficacy against viral variants. For example, a trial conducted in South Africa showed 10.4% efficacy for the AstraZeneca vaccine Vaxzevria against mild to moderate infections caused by the Beta (B.1.351) variant.
- ***Delayed onset of protection.*** The peak neutralizing antibody response conferred by currently available vaccines is usually 10 to 14 days after the final dose of the vaccine, resulting in a period of time during which an individual can be infected with SARS-CoV-2 and develop COVID-19, despite having received the vaccine. Furthermore, given that certain vaccines require two doses, three to four weeks apart, the total time from the first vaccine dose to peak neutralizing antibody response can be several weeks.
- ***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. Preliminary data shows that these individuals mount poor antibody responses to mRNA vaccines, demonstrating the unmet medical need for effective preventative options for immunocompromised populations.
- ***Perceived tolerability and safety.*** While currently available vaccines have demonstrated acceptable safety and tolerability profiles, there continue to be negative perceptions of vaccine safety that have been exacerbated by government holds on certain vaccines, as well as widespread publicity regarding rare, but potentially severe, side effects.
- ***Vaccine hesitancy.*** Due to a constellation of perceived safety, side effect and quality concerns, according to an April 2021 survey conducted by CBS News, approximately 40% of Americans are reluctant to receive a COVID vaccine, including 22% who outright refuse to receive a vaccine. As a result, as of June 20, 2021, 45% of the U.S. population had been fully vaccinated. Globally, vaccine hesitancy is consistent with the U.S. figures. In a Gallup poll conducted in April 2021, in 79 out of 117 countries surveyed, the number of people who said they were willing to be vaccinated was below 70%.
- ***Durability of response, including the potential need for booster shots.*** The length of protection conferred by currently available vaccines is uncertain, and recent announcements from the makers of some of these vaccines indicate that periodic administration of booster vaccines will likely be required, similar to the influenza vaccine.
- ***Ability to achieve herd immunity.*** Many countries, including developed nations, have low vaccination rates due to multiple factors, such as limited vaccine availability as well as vaccine hesitancy. For example, only 33% of available vaccine doses had been purchased by low- and middle-income countries, which constitute over 80% of the global population. As of June 20, 2021, less than 10% of the world's population had been fully vaccinated. As long as significant numbers of people globally are not vaccinated, COVID-19 and disease caused by SARS-CoV-2 variants can continue to circulate. In addition, vaccination of the pediatric population is believed to be critical to achieving herd immunity.
- ***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

## [Table of Contents](#)

transmitting SARS-CoV-2. Given that approximately 25% of the global population is under the age of 15, herd immunity is unlikely to be achieved until effective options for prevention are widely adopted in this population. Although an EUA was recently granted for use of the Pfizer/BioNTech vaccine in adolescents aged 12 to 15 years, the timing of vaccine availability for younger school-age children remains fluid. Further, data collected in April 2021 by the Kaiser Family Foundation suggest that only about a third of parents plan to vaccinate their children when vaccines first become available to them. The anticipated delay in widespread childhood vaccination, coupled with the rise in new variants relatively resistant to vaccine-induced immunity, have the potential to further impact the achievement of herd immunity.

### ***mAbs for Treatment of COVID-19***

Recent approvals of mAbs for the treatment of Ebola Virus Disease and multi-drug resistant human immunodeficiency virus, or HIV, infection demonstrate their promise for the treatment of viral infections. Some SARS-CoV-2 mAb therapies, either as a monotherapy or a combination cocktail, have been granted an EUA in the United States and India and are available for use as unauthorized products in certain EU member states for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. These available mAbs include bamlanivimab, bamlanivimab/etesevimab, casirivimab/imdevimab, regdanvimab, and sotrovimab.

### ***Limitations of Currently Available mAbs***

The recent emergence of SARS-CoV-2 variants has attenuated *in vitro* neutralization activity of certain currently available mAbs. For example, the U.S. Food and Drug Administration, or the FDA, recently revoked the EUA for bamlanivimab due to its lack of *in vitro* activity against key variants of concern as a single agent and distribution of a second agent, bamlanivimab/etesevimab, was paused in the United States due to data showing that the combined frequency of two variants resistant to this product, the Gamma (P.1) and Beta (B.1.351) variants, exceeded 11% in the United States. Consistent with *in vitro* data showing more pronounced loss of neutralization activity for casirivimab and bamlanivimab/etesevimab against the Gamma variant compared to the Alpha variant, preliminary real-world use data from Italy suggest lower clinical efficacy for casirivimab/imdevimab and bamlanivimab/etesevimab against infections due to the Gamma 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. Publications regarding real-world use of these agents under EUA show that large numbers of otherwise eligible patients who were referred for therapy ultimately did not receive it. 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 difficulty accessing treatment. We anticipate that these same limitations will apply to any IV-administered mAbs that may be authorized or approved for the prevention of COVID-19. Furthermore, in the setting of prevention, mAbs without sufficiently long half-lives will likely require frequent and periodic administration in order to achieve long-lasting protection.

### **Our Approach to COVID-19 and Development of Coronavirus mAbs**

Our vision is to discover, develop and commercialize antibody-based solutions not only for the current COVID-19 pandemic but also to address future potential coronavirus outbreaks. To enable this vision, our discovery efforts are focused on broadly neutralizing antibodies that target conserved epitopes across multiple members of the coronavirus family. We believe that a mAb therapy with the following characteristics will have the potential to address the limitations of currently available treatment and prevention options for COVID-19 as well as future diseases that may arise from SARS-like viruses with pandemic potential:

- High potency and broad neutralizing activity to address SARS-CoV-2, including variants of concern, and additional SARS-like viruses;
- Multiple mechanisms of action, including direct virus neutralization by blocking viral entry into the host cell and elimination of infected host cells through innate immune effector activity to clear infection;



## Table of Contents

- Convenient outpatient administration as a single-dose IM injection; and
- Ability to provide both rapid and durable protection with potential protection against COVID-19 for up to one year.

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 differentiate our approach include:

- **Recognition of the importance of broadly neutralizing antibodies:** From the outset, 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 and other viral outbreaks will continue to emerge.
- **Industry-leading B-cell mining, protein engineering and developability screening capabilities through our partnership with Adimab:** We leverage nature's solutions using Adimab's deep B-cell mining capabilities to isolate broadly neutralizing antibodies from a disease survivor of an earlier SARS infection. We then utilize Adimab's leading protein engineering capabilities to improve the potency, breadth and half-life of the antibody candidates we advance into preclinical development. We specifically engineer our antibodies to extend their half-lives without affecting Fc-mediated innate immune effector activity. In addition, we have access to Adimab's extensive suite of developability assays that allow for selection of lead candidates most likely to be readily manufactured and formulated for use in humans.
- **Reduced risk of clinical resistance:** We are developing antibodies that target conserved residues in the receptor-binding domain, or RBD, of the viral S protein. Importantly, these residues are distinct from those recognized by more narrowly targeted SARS-CoV-2-specific antibodies that are currently available or in development. In addition, the residues that our antibodies target are not readily targeted by antibodies induced by natural infection, which are referred to as public antibodies. These two factors suggest that the residues our antibodies target are less likely to mutate, which we believe will reduce the risk of resistance to our antibodies. In contrast, many of the SARS-CoV-2-specific antibodies that are currently available or in development target residues that are both variable and commonly recognized by public antibodies. The combination of variable residues and immune selection pressure exerted by antibodies elicited by vaccination and natural infection has led to the emergence of SARS-CoV-2 variants with reduced susceptibility to some of the mAbs currently available under EUA. In contrast, our broadly neutralizing antibodies, including ADG20, have maintained neutralizing activity *in vitro* against these known and emerging variants. Furthermore, the frequency of circulating variants with mutations in the residues targeted by our antibodies has been extremely low.

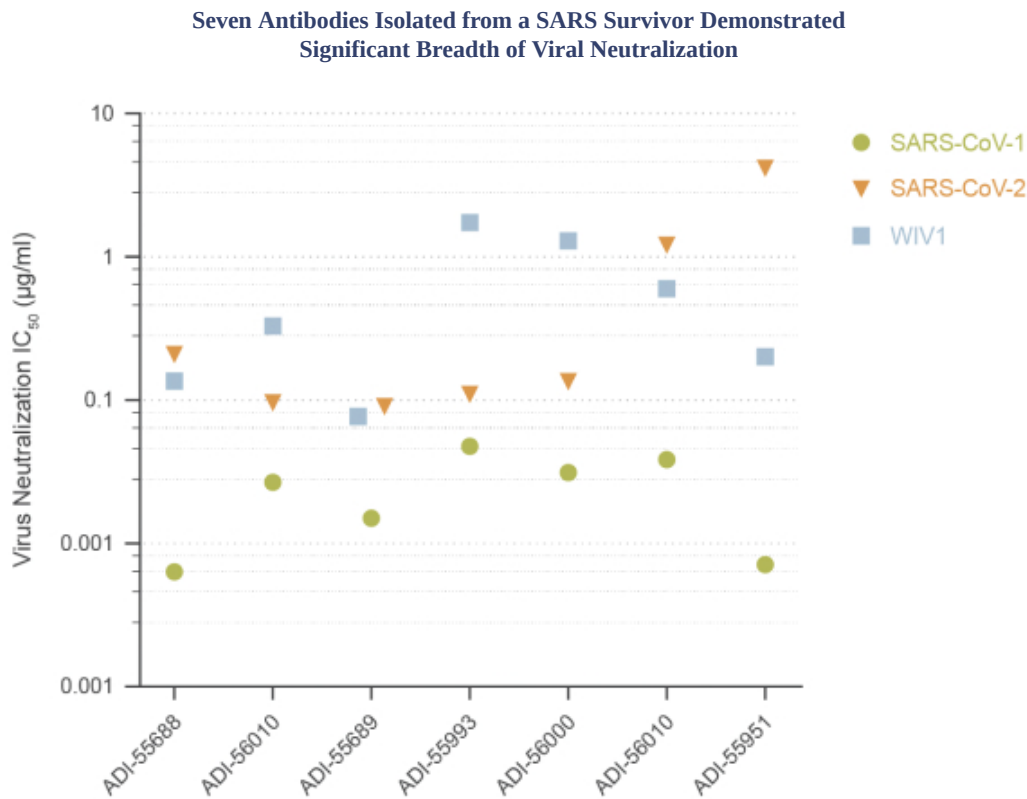
### ***Our Discovery of ADG20***

Our founding scientists designed and engineered ADG20 with the goal of creating a highly active and broad mAb-based therapeutic candidate for both the treatment and prevention of COVID-19. They focused on isolating an antibody capable of broadly neutralizing the entire viral class of SARS-like viruses from the sarbecovirus lineage, including diverse family members such as SARS-CoV-1, WIV1, SHC014 and SARS-CoV-2, as opposed to only neutralizing SARS-CoV-2.

To achieve this objective, a blood sample was obtained from a survivor of the 2003 SARS outbreak who had never been exposed to SARS-CoV-2. After purification, 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. These antibodies were then evaluated for their breadth of neutralization against SARS-CoV-1, SARS-CoV-2 and

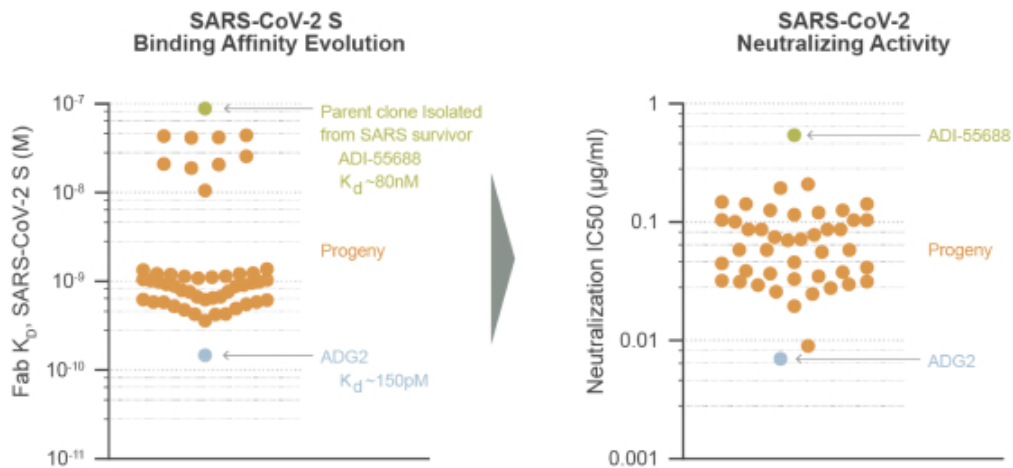


WIV1. Out of the 200 antibodies, seven demonstrated broad neutralization potency, as shown in the graphic below.



Rather than immediately advancing one of these seven candidates into clinical development, we opted to improve the binding affinities, and thus neutralizing activities, of three of these antibodies using the Adimab protein engineering platform. Affinity maturation allowed us to increase the SARS-CoV-2 S protein binding affinity and neutralization potency of ADI-55688 by as much as 500- and 77-fold, respectively, as shown in the graphic below. Based on this enhanced profile, we selected to evaluate ADG2, the ADI-55688 progeny with the most improved binding affinity and neutralization potency, in additional preclinical studies.

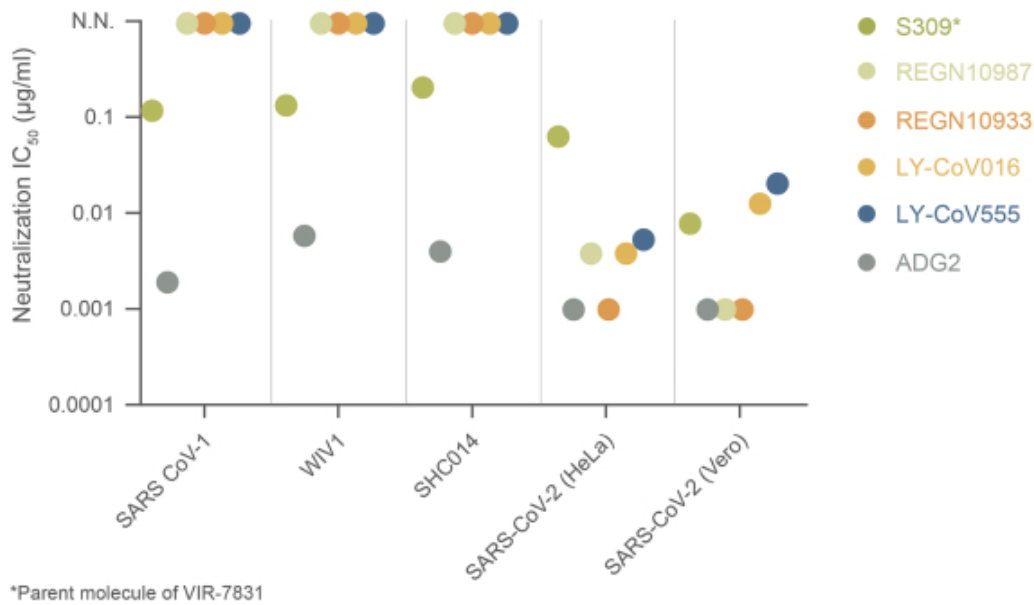
**Protein Engineering Substantially Improved Binding to and Neutralization of SARS-CoV-2**



To determine whether ADG2 retained its broad neutralization capability, 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. Of the Clade 1 viruses, authentic virus neutralization assays, which represent the relevant assays to evaluate *in vitro* neutralization activity, are only available for SARS-CoV-1, SARS-CoV-2, WIV1 and SHC014. Among the Clade 1 viruses, SHC014 is the most genetically divergent from SARS-CoV-2, and therefore, the ability to neutralize both SARS-CoV-2 and SHC014 suggests an ability to neutralize the majority of viruses in the clade.

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**



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 COVID-19 for up to 12 months, which resulted in our lead product candidate, ADG20.

**ADG20: Our Solution for the Treatment and Prevention of COVID-19**

ADG20, our lead product candidate, is designed to be a potent, broadly neutralizing antibody for both the treatment and prevention of COVID-19, including disease caused by variants, as either a single or combination agent. Unlike other antibody-based therapies specifically targeting SARS-CoV-2, ADG20 has demonstrated in non-clinical studies an ability to neutralize SARS-CoV-2, including variants of concern, as well as a broad range of sarbecoviruses with neutralization potency at IC<sub>50</sub> of approximately 0.01 mcg/mL or less in live-virus cellular assays. In addition, ADG20 can be conveniently administered as a single-dose IM injection. We believe these and other attributes of ADG20 differentiate it from other antibodies that are either available under EUA or in development to address COVID-19.

Our clinical development plan for ADG20 includes two global clinical trials designed to demonstrate the safety and efficacy of ADG20 for the treatment and prevention of COVID-19, respectively. We have completed enrollment in our first-in-human Phase 1 clinical trial in healthy volunteers, which demonstrated that a single-dose of ADG20 was well tolerated at doses up to 500 mg IV and 600 mg IM and that the initial pharmacokinetic profile was consistent with an extended half-life mAb. In addition, the serum virus neutralizing antibody titers measured the day following administration of ADG20 were similar to or exceeded peak serum neutralizing antibody titers generated after two doses of mRNA or adenovirus-based COVID-19 vaccines. We are conducting two separate Phase 2/3 clinical trials to evaluate ADG20 for the treatment of COVID-19, which we refer to as our STAMP trial, and for the prevention of symptomatic COVID-19, which we refer to as our EVADE trial. For the treatment of mild to moderate COVID-19 in patients at high risk of disease progression, our STAMP trial is designed to provide a path to applying for EUA and/or filing a BLA for marketing approval in 2022, and commercial launch thereafter, if ADG20 is approved. We may not meet our time frames for submission for an EUA or a BLA, and if we do meet such timelines, there is no guarantee the FDA would approve our submission,

or on the time frame we have indicated. Our EVADE trial is designed to evaluate the prevention of COVID-19 in both post-exposure and pre-exposure populations. We are also developing a clinical development strategy to support the use of ADG20 in the pediatric population.

### **Key Advantages of ADG20**

We believe ADG20 will have the following key clinical and commercial advantages:

- **Broadly neutralizing activity across sarbecoviruses.** From the outset, we selected and engineered the mAb that became ADG20 specifically for its ability to broadly neutralize not only SARS-CoV-2 and its variants, but also additional members of the sarbecovirus lineage.
- **Rapid onset of protection.** Currently available COVID-19 vaccines can take several weeks, and often require multiple doses, to induce peak neutralizing antibody response. As a mAb, ADG20 has the potential to confer more rapid protection post-dose against COVID-19 and its complications.
- **Differentiated durability.** ADG20 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 ADG20 may result in durable serum levels that we believe may provide protection for up to 12 months.
- **Convenient, single-dose IM injection for use in the outpatient setting.** Currently available COVID-19 mAbs are administered via IV infusions that require specialized facilities that are properly equipped to accommodate IV infusions in actively infected patients, which may lead to a delay in administration. In contrast, the low viscosity, high concentration formulation and high potency of ADG20 allow it to be delivered as a convenient, single-dose IM injection in traditional outpatient settings.
- **Ability to both complement and supplement currently available COVID-19 vaccines, including for immunocompromised individuals.** ADG20 is designed to provide convenient, rapid and durable protection against COVID-19 and its complications, including for vulnerable individuals unlikely to mount a protective immune response to vaccines, such as the immunocompromised population. ADG20 has the potential to be used as either a complement (i.e., an alternative) or supplement (i.e., add-on) to vaccines, as well as a means to provide protection following an exposure to an individual with laboratory-confirmed COVID-19.
- **High titer, high yield manufacturing process.** We have developed a proprietary process to manufacture ADG20 at a large scale that is suitable for broad commercialization and enables a relatively low cost of goods.
- **Potential for affordability.** An antibody therapy with a low cost of goods that is administered as a single IM injection with potential durability for up to 12 months has the potential to offer payors, providers and patients an affordable option to treat and prevent COVID-19. Recent 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 ADG20's potential for affordability may allow for greater pricing flexibility to encourage broader access to ADG20 and appropriate use by government and private payors, physicians and patients.
- **Standard refrigeration requirements to facilitate worldwide distribution and storage.** ADG20 may be conveniently stored under standard refrigerated conditions during distribution and prior to administration. We are in the process of confirming the long-term stability of ADG20 in sterile liquid form under refrigerated conditions.
- **Long shelf life to enable stockpiling.** ADG20 has the potential to be developed as a lyophilized formulation to further extend the shelf life of the drug product under refrigerated conditions. Through a combination of the lyophilized form and the long-term frozen storage of the drug substance

intermediate, we believe the shelf life of ADG20 can be further extended to enable stockpiling initiatives to address future potential coronavirus pandemics.

**Mechanism of Action**

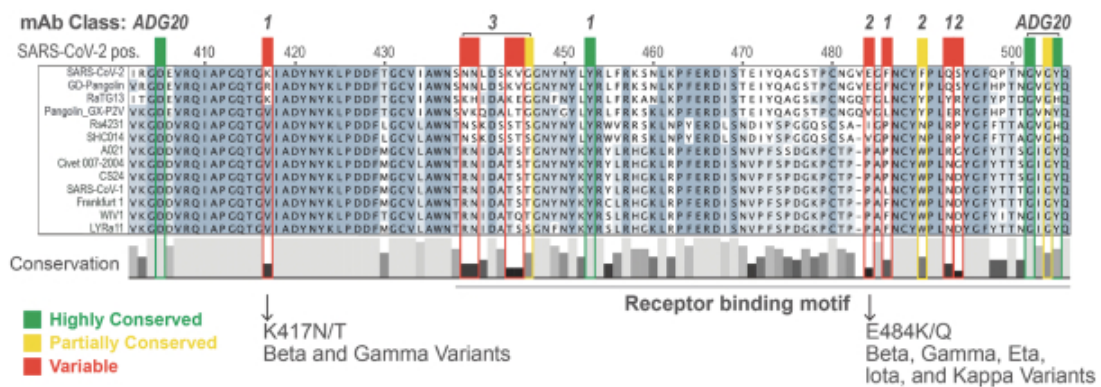
ADG20 has the potential to impact viral replication and subsequent disease through multiple mechanisms of action, including direct blocking of viral entry into the host cell, or neutralization, and elimination of infected host cells through Fc-mediated innate immune effector activity. The majority of antibodies, including ADG20, that neutralize SARS-CoV-2 target the S protein, and more specifically, target the surface that overlaps with the hACE2 receptor binding site.

Public antibodies that are commonly elicited by natural SARS-CoV-2 infection have been categorized into three classes based on their shared epitopes and escape mutations. These public antibodies target variable amino acid residues that are likely not important for viral fitness, and thus are susceptible to mutation. A subset of the mutations, including those at the E484K, L452R and K417N/T residues that are present in multiple variants of concern, confers resistance to class 1 and class 2 antibodies, which likely emerged in response to immune pressure exerted on these amino acid residues by the commonly induced public antibodies.

Class 1 antibodies, such as etesevimab, or LY-CoV016, and casirivimab, or REGN10933, are impacted by escape mutations at amino acid residue K417N/T, which are found in the Beta (B.1.351) and Gamma (P.1) variants. Class 2 antibodies, such as bamlanivimab, or LY-CoV555, and tixagevimab, or COV2-2196, are impacted by escape mutations at amino acid residue E484, which are found in Beta (B.1.351), Gamma (P.1), Iota (B.1.526) and Kappa (B.1.617.1) variants. Class 3 antibodies, such as imdevimab, or REGN10987, bind largely to variable residues and are thus associated with multiple potential routes of escape. As of May 5, 2021, variants containing mutations at key Class 3 residues have been detected in global sequence databases at frequencies exceeding 5.5%.

The graphic below shows the amino acid sequences for RBDs of Clade 1 sarbecoviruses with SARS-CoV-2 in the top row. The graphic also shows the specific amino acid residues targeted by Class 1-3 antibodies and ADG20. When the amino acid residue at a certain position is the same or biochemically similar across viruses, it is considered to be conserved. These conserved residues are highlighted in the graphic below in green and yellow. When the amino acid residue at a certain position changes across viruses, it is considered variable. These variable residues are highlighted in the graphic below in red. Antibodies targeting residues that are conserved are more likely to be broadly neutralizing whereas those that target variable residues are more likely to lose effectiveness against viruses that have a different residue at that position.

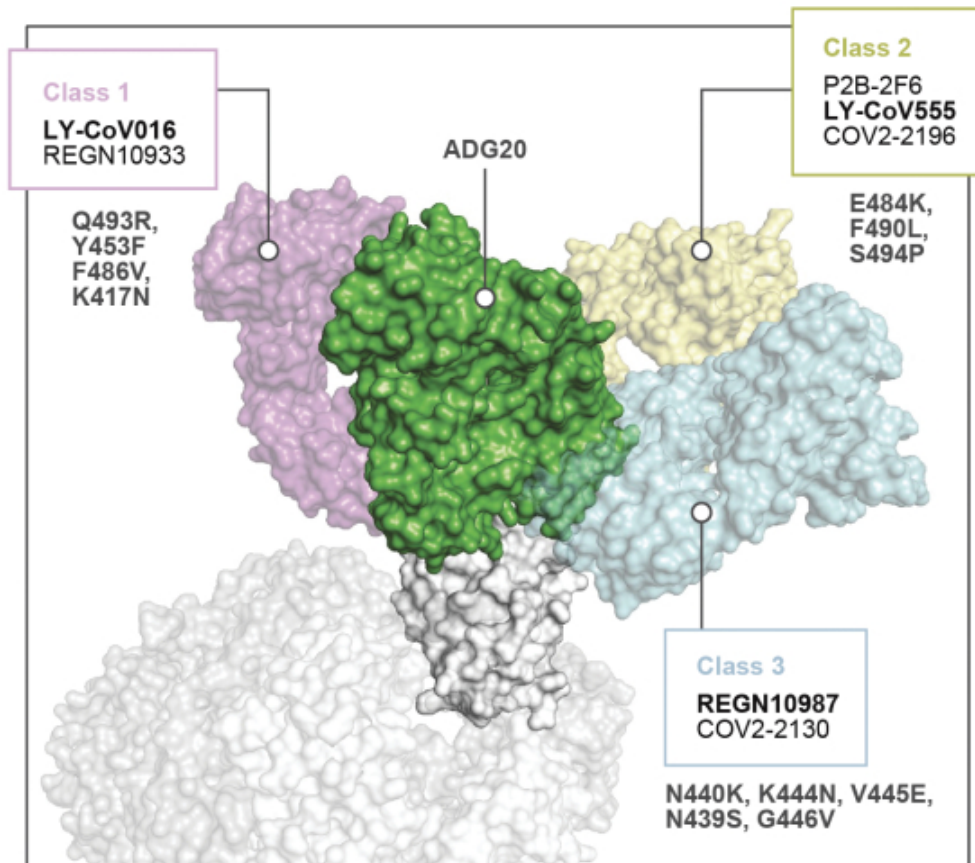
**Class 1-3 Antibodies Target Variable Residues Associated with Viral Escape**



## [Table of Contents](#)

In contrast to Class 1-3 antibodies, ADG20 employs a unique binding strategy. The amino acid residues that ADG20 engages are conserved, as highlighted in green and yellow above, 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 vitro*, serial viral passaging of virus in the presence of ADG20 leads to the emergence of mutations at position G504. As of June 15, 2021, mutations at this position were present at extremely low frequency (0.004%) among circulating SARS-CoV-2 isolates. In contrast, Class 1-3 antibodies that lack neutralization breadth typically select for multiple mutations in serial viral passage experiments, many of which are present at high frequency among circulating SARS-CoV-2 isolates, such as E484K and K417N. In addition, the binding site engaged by ADG20 is not readily targeted by public antibodies, which significantly limits immune pressure at these residues. A comparison of ADG20's 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.

### ADG20 Targets a Unique Site on the RBD of the SARS-CoV-2 S Protein



In addition to neutralizing activity, ADG20 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**

ADG20 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 ADG20 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 ADG20 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, ADG20 has demonstrated neutralizing activity against SARS-CoV-2 and the 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, ADG20 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 ADG20 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 Demonstrated Potency and Broad Neutralization of SARS-CoV-2 and All 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 ADG20 against the Victoria virus strain, which is similar to the original Wuhan-Hu-1 virus strain, and the Alpha (B.1.1.7), Beta (B.1.351) and Gamma (P.1) and Delta (B.1.617.2) variants. ADG20 demonstrated robust viral neutralization activity against the original Victoria virus as well as all four variants. As shown in the table below, ADG20 displayed IC<sub>50</sub> values of 0.01 mcg/mL or less and 99-100% maximum neutralization plateaus, demonstrating near complete neutralization of the total viral population for all five virus strains. In contrast, a subset of SARS-CoV-2-specific antibodies displayed substantial loss of neutralization activity against a subset of variants, with IC<sub>50</sub> values exceeding 1 mcg/mL. The other antibodies in the table below were selected for inclusion because they represent mAb therapies that are either in late-stage development or have been granted an EUA in the United States and India or are available for use as unauthorized products in certain EU member states for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression.

**ADG20 Displays Neutralizing Activity Against SARS-CoV-2 and Variants of Concern**

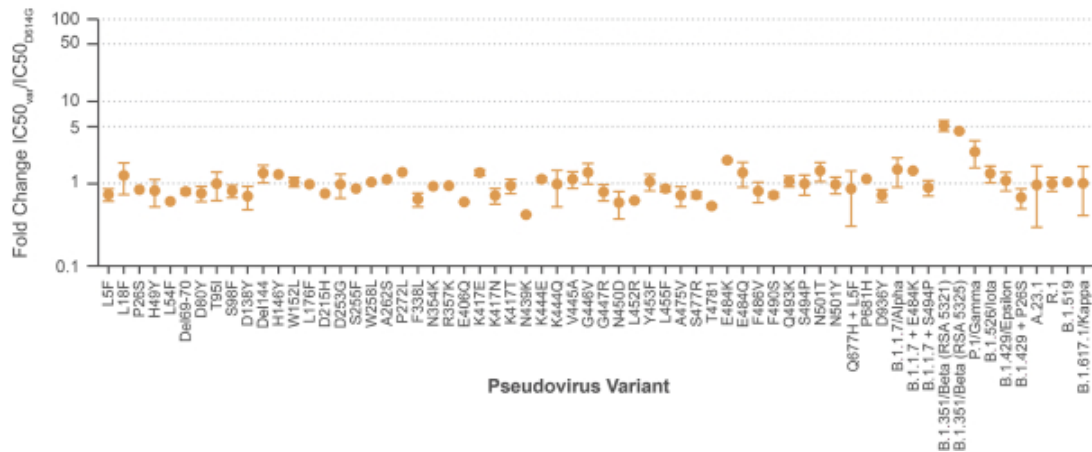
	IC <sub>50</sub> (mcg/mL)					Neutralization Plateau (%)				
	Victoria	Alpha B.1.1.7	Beta B.1.351	Gamma P.1	Delta B.1.617.2	Victoria	Alpha B.1.1.7	Beta B.1.351	Gamma P.1	Delta B.1.617.2
<b>ADG20</b>	0.004	0.006	0.010	0.009	0.006	100	100	100	99	100
<b>AZD1061</b>	0.013	0.012	0.014	0.007	0.038	100	100	100	100	94
<b>AZD8895</b>	0.005	0.011	0.046	0.046	0.003	100	100	100	90	100
<b>REGN10987</b>	0.032	0.028	0.007	0.013	0.017	97	95	97	93	97
<b>REGN10933</b>	0.004	0.014	3.284	6.177	0.003	100	100	N/A	N/A	100
<b>LY-CoV555</b>	0.006	0.009	>10	>10	8.311	100	100	N/A	N/A	N/A
<b>LY-CoV016</b>	0.034	3.225	>10	>10	0.012	100	N/A	N/A	N/A	100
<b>S309</b>	0.040	0.078	0.082	0.076	0.113	80	89	95	85	92

In addition, the neutralization potency and breadth of ADG20 was evaluated by an independent U.S. government laboratory against a panel of 64 SARS-CoV-2 pseudovirus variants, including the Epsilon (B.1.427/429), Iota (B.1.526) and Kappa (B.1.617.1) 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 incorporating single or double amino acid substitutions and spike proteins



encoding the full sets of mutations observed in emerging variants of concern and variants of interest. As shown in the graphic below, ADG20 maintained neutralization activity across all variants tested to date, with IC<sub>50</sub> values within approximately 0.4- to 5.1-fold relative to the reference D614G strain. The D614G strain is a variant of the original Wuhan-Hu-1 strain that emerged in the early phases of the pandemic and rapidly outcompeted the original strain to become the globally dominant variant by mid-2020. Moreover, emerging variants, such as Alpha (B.1.1.7) and Beta (B.1.351), all harbor the D614G mutation, making it a suitable reference for comparison.

**ADG20 Displayed Neutralization Activity Against a Broad Panel of SARS-CoV-2 Variants**

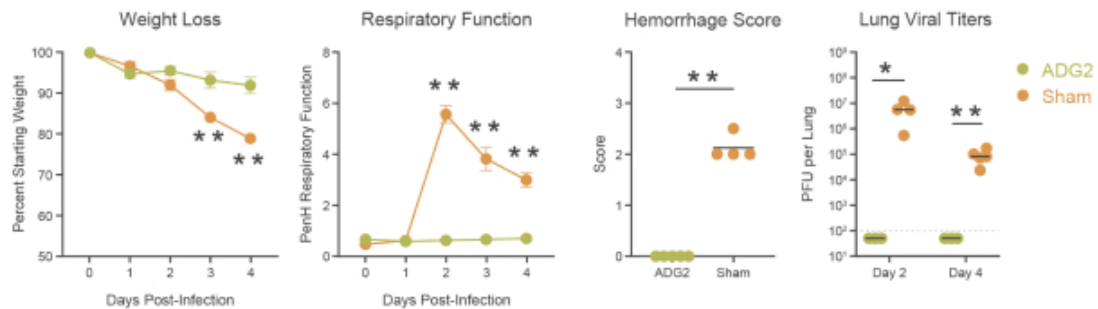


*In Vivo Studies of ADG2 and ADG20 Demonstrated Efficacy in Treatment and Prevention of SARS-CoV-2 Infection*

To determine whether ADG2, the parent molecule of ADG20, could prevent SARS-CoV-1 and SARS-CoV-2 infection and associated disease in mice, we conducted an *in vivo* preclinical study where Balb/c mice were administered 200 µg of ADG2 or placebo, or sham, via intraperitoneal injection and then challenged 12 hours later with either mouse-adapted, or MA, SARS-CoV-1 or SARS-CoV-2 via the intranasal route. Body weight, respiratory function and lung histopathology were evaluated. In this preclinical study, ADG2 administered prophylactically protected healthy adult mice from weight loss, respiratory distress and pulmonary hemorrhage associated with infection due to MA SARS-CoV-1 or SARS-CoV-2, as shown below. Prophylactic treatment with ADG2 also prevented viral replication in the lungs post-infection. In contrast, prophylactic sham treatment resulted in deteriorations across all four parameters.

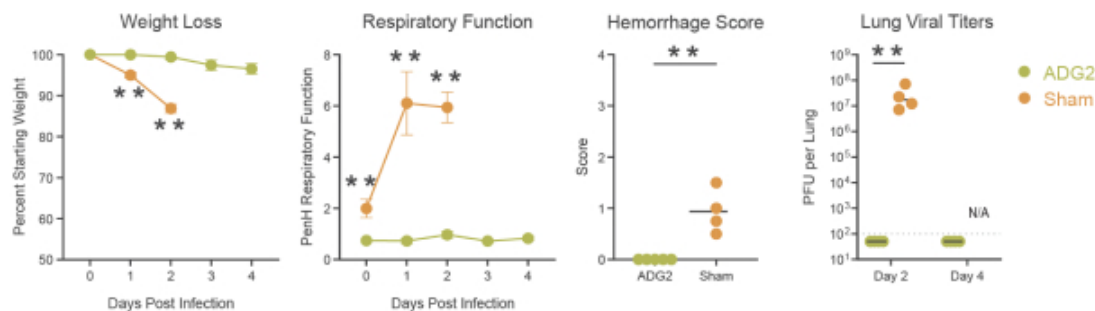
**ADG2 Provides Complete Protection Against Severe SARS-CoV-2 and SARS-CoV-1 Disease in a Mouse Model**

**SARS-CoV-2 model:**





**SARS-CoV-1 model:**

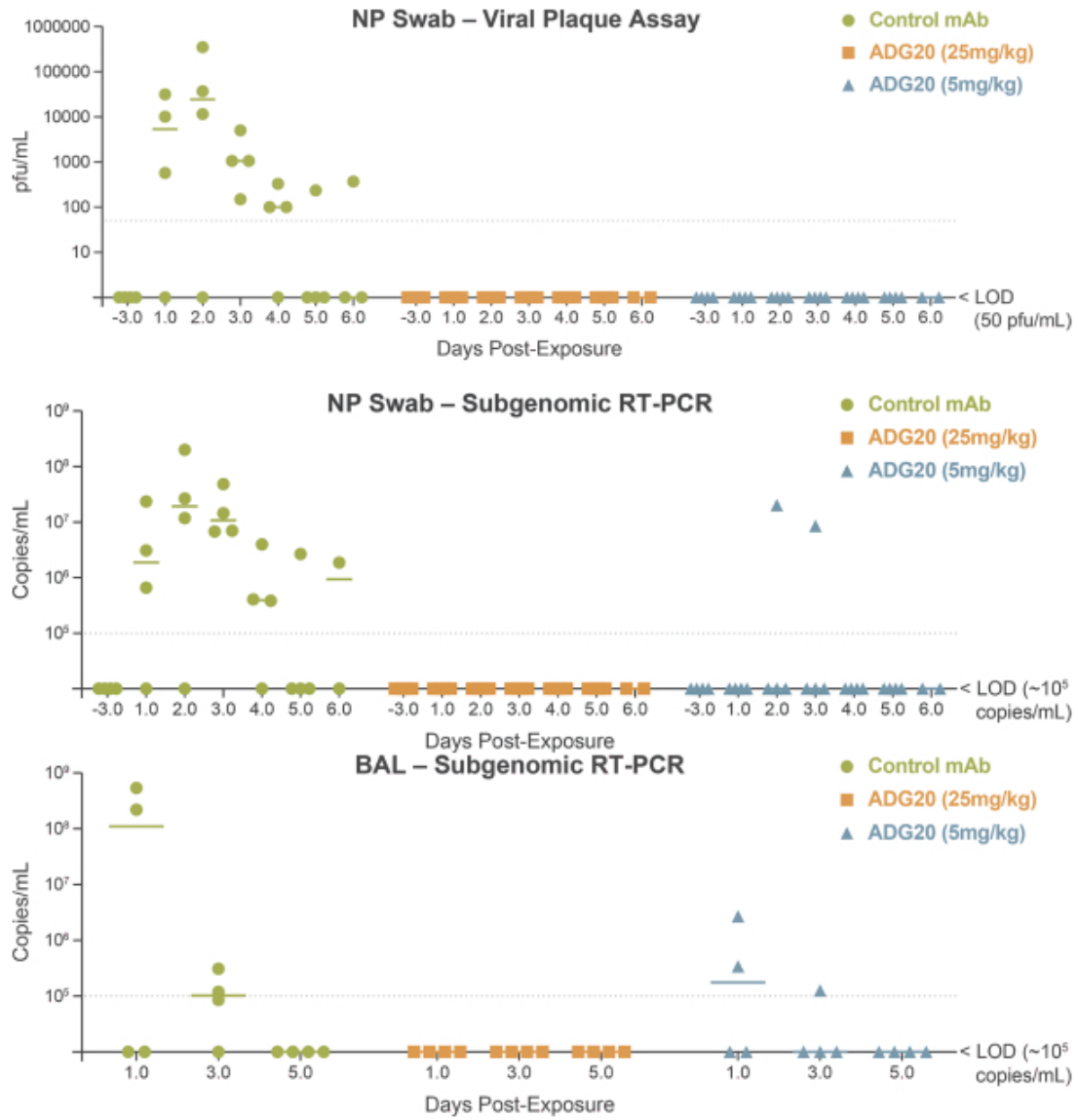


To determine whether a low dose of ADG2 could provide therapeutic benefit against SARS-CoV-2-associated disease in mice, we conducted an *in vivo* preclinical study where Balb/c mice were challenged intranasally with MA SARS-CoV-2 and then treated with either 200 µg of ADG2 or placebo via intraperitoneal injection 12 hours following challenge. Compared to placebo, ADG2 resulted in less weight loss and was associated with improved respiratory function and histological signs of hemorrhage. In addition, treatment with ADG2 also resulted in a significant reduction in lung viral loads at four days post-infection relative to treatment with placebo.

In conjunction with the United States Army Medical Research Institute for Infectious Diseases, or USAMRIID, we conducted two preclinical studies to investigate the efficacy of ADG20 in the prevention of SARS-CoV-2 infection in hamsters and non-human primates, or NHPs. A dose ranging study of ADG20 in hamsters was conducted to investigate the *in vivo* efficacy of ADG20 in preventing SARS-CoV-2 infection and to evaluate the potential for antibody-dependent enhancement, or ADE, of infection at sub-neutralizing, or sub-efficacious, concentrations of ADG20. The preclinical study included six cohorts, with four cohorts administered differing doses of ADG20 and two cohorts administered a control antibody. The antibodies were administered 24 hours prior to an intranasal viral challenge and viral load was measured in lungs harvested on days three or six post-challenge. This preclinical study demonstrated that ADG20 inhibits viral replication in a dose-dependent manner with no evidence of ADE of viral replication at sub-efficacious serum concentrations.

We also conducted a preclinical study with USAMRIID to investigate the efficacy of ADG20 in the prevention of SARS-CoV-2 infection in NHPs. Three cohorts were dosed with 5 mg/kg of ADG20, 25 mg/kg of ADG20 or an irrelevant control antibody through IV infusion three days prior to combined intranasal and intratracheal challenge with SARS-CoV-2/WA-1, a strain similar to the original Wuhan-Hu-1 strain. Swabs of the nasopharyngeal cavities were taken daily on days one through six post-challenge to assess viral load by both viral plaque assay, which measures levels of infectious virus, and RT-PCR of subgenomic viral RNA, which measures active viral replication. Viral replication in the lungs was also evaluated by subgenomic RT-PCR on bronchioalveolar lavage, or BAL, fluid collected on days one, three and five. As shown in the graphic below, persistent viral replication was detected through day six in the nasopharyngeal cavities of all control-treated animals. In contrast, complete protection against viral replication was observed in all respiratory compartments at the 25 mg/kg dose level. Substantial protection was also observed at the 5 mg/kg dose level, as demonstrated by reduced viral loads and accelerated viral clearance compared to control-treated animals.

**ADG20 Provides Prophylactic Protection in an NHP Model**



**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 recent clinical experience with

[Table of Contents](#)

SARS-CoV-2 mAbs as well as prior experience with the use of neutralizing antibodies for the treatment and prevention 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.

**ADG20 for Treatment and Prevention of COVID-19**

ADG20 Target Populations						
	Uninfected	Asymptomatic or Presymptomatic	Mild Illness	Moderate Illness	Severe Illness	Critical Illness
SARS-CoV-2 RNA Testing	Negative	Positive	Positive	Positive	Positive	Positive
Clinical Features	No symptoms	No symptoms	Mild symptoms (eg, fever, cough, change in taste or smell), no shortness of breath	Clinical or radiographic evidence of pneumonia; oxygen saturation $\geq$ 94%	Oxygen saturation < 94%; elevated respiratory rate; extensive lung involvement	Respiratory failure, shock, multiple organ dysfunction or failure
Proposed Disease Pathogenesis		Viral Replication			Inflammation	

As shown below, our clinical development plan for ADG20 includes a series of clinical trials to demonstrate the potential of ADG20 for both the treatment and prevention of COVID-19 in adults and adolescents. We have completed enrollment in our first-in-human Phase 1 clinical trial in healthy volunteers, which demonstrated that ADG20 was well tolerated and displayed a pharmacokinetic profile consistent with an extended half-life mAb. In addition, serum virus neutralizing antibody titers measured the day following administration of ADG20 were similar to or exceeded peak serum neutralizing antibody titers generated after two doses of mRNA or adenovirus-based COVID-19 vaccines. For the treatment of mild to moderate COVID-19 in patients at high risk of disease progression, we are conducting our combined Phase 2/3 STAMP trial that is designed to provide a path to applying for EUA and/or filing a BLA for marketing approval in 2022, and commercial launch thereafter, if ADG20 is approved. We may not meet our time frames for submission for an EUA or a BLA, and if we do meet such timelines, there is no guarantee the FDA would approve our submission, or on the time frame we have indicated. For the prevention of symptomatic COVID-19, we are conducting our combined Phase 2/3 EVADE clinical trial in both post-exposure and pre-exposure populations. If our STAMP and EVADE trials are successful, we believe ADG20 has the potential to be approved for both the treatment and prevention of COVID-19 in the United States, potentially preceded by an EUA for the treatment of mild to moderate COVID-19 in patients at high risk of disease progression. Importantly, given the global impact of COVID-19, we also plan to seek approvals outside the United States. In addition, we are developing a clinical plan to support the use of ADG20 in the pediatric population for both the treatment and prevention of COVID-19.

**Our Clinical Development Program for ADG20**

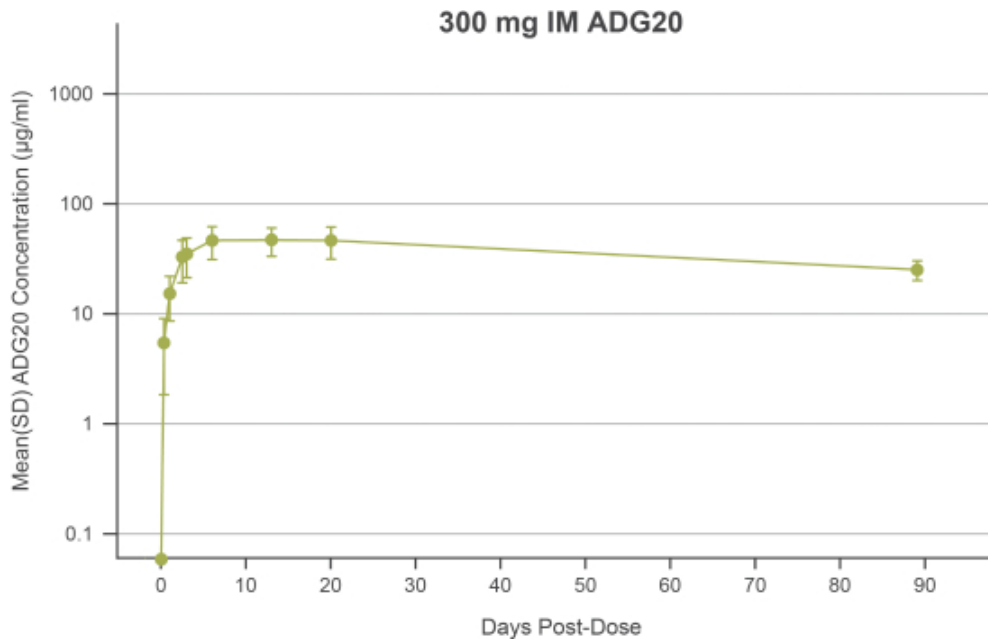
	<b>First-in-Human Trial</b>	<b>Treatment Trial</b>	<b>Prevention Trial</b>
		<b>STAMP</b>	<b>EVADE</b>
<b>Population(s)</b>	Healthy adult participants with no evidence of prior or current SARS-CoV-2 infection	Ambulatory patients with mild or moderate COVID-19 and high risk of disease progression based on age or co-morbid conditions (eg. obesity, diabetes, chronic kidney disease)	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)
<b>Primary Endpoint(s)</b>	Safety and tolerability of single IM and IV doses of ADG20	COVID-19 related hospitalization or all cause death through Day 29	RT-PCR confirmed symptomatic COVID-19 through Day 28 (post-exposure) or 6 months (pre-exposure)

*First-in-Human Phase 1 Dose Escalation Clinical Trial*

In February 2021, we initiated a Phase 1 single ascending-dose escalation clinical trial of ADG20, which is designed to evaluate the safety, tolerability and pharmacokinetic properties of ADG20, along with serum virus neutralizing antibody titers. We have completed enrollment of 30 healthy volunteers across three cohorts, with ten participants per cohort randomized 8 to 2 to ADG20 or placebo, respectively. Each participant received a single IM or IV administration of either 300 mg IM, 500 mg IV or 600 mg IM of ADG20 or placebo. As of June 14, 2021, no serious adverse events, study drug-related adverse events, hypersensitivity reactions, infusion-related reactions or injection site reactions were reported in any study participant. All reported adverse events were mild in severity and resolved.

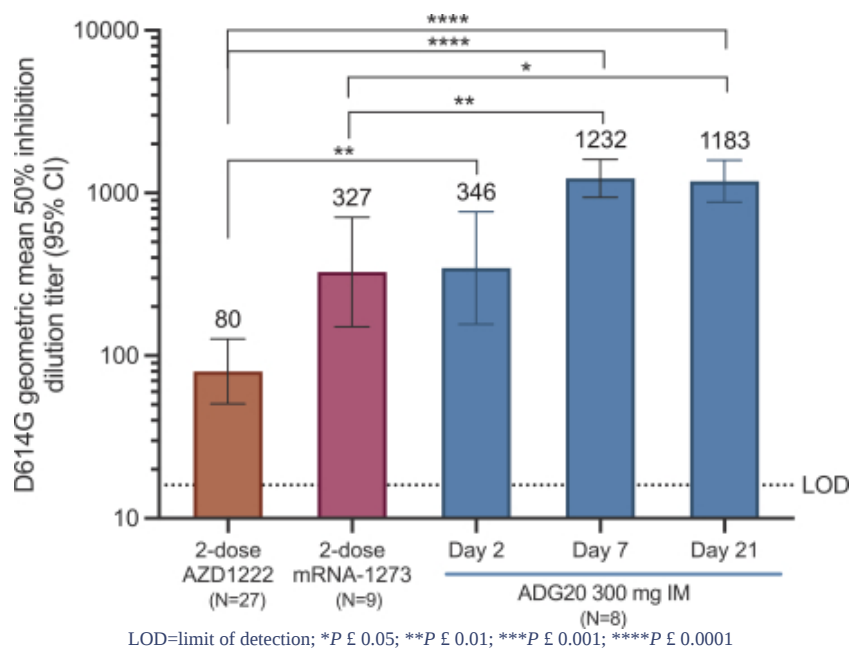
The preliminary pharmacokinetic profile approximately 3 months following administration of a single 300 mg IM dose is shown in the illustration below. The observed data are consistent with the pharmacokinetic profile predicted by a physiologically based pharmacokinetic model used to guide dose selection and project a prolonged serum half-life of approximately 60 to 100 days. Based on the model predicted pharmacokinetic profile, the median ADG20 serum concentration at 52 weeks, or approximately 12 months, is projected to exceed the ADG20 *in vitro* IC<sub>90</sub> by approximately 100-fold, supporting the potential for a single IM injection to provide protection from COVID-19 for up to 12 months. Preliminary observed ADG20 pharmacokinetic profiles were dose proportional across the other dose levels tested and were also well predicted by the model.

**Preliminary Pharmacokinetic Profile of a Single 300 mg IM Dose of ADG20**



Serum virus neutralizing antibody titers are believed to be a key correlate of protection against COVID-19. Using an authentic virus neutralization assay, we compared serum virus neutralizing antibody titers on days 2, 7 and 21 following a single 300 mg IM dose of ADG20 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 ADG20, 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 ADG20 were significantly higher than peak titers generated by either vaccine and were maintained out to day 21. Using the quantitative pharmacology model, median ADG20 serum neutralizing antibody titers at six months are projected to remain within the range measured at peak for the mRNA-1273 vaccine recipients. At 52 weeks, or approximately 12 months, post-dosing median titers were projected to remain above a threshold associated with protection from SARS-CoV-2 infection in non-human primates administered purified IgG from previously infected animals. These data further support the potential for a single 300 mg IM injection of ADG20 to provide protection against COVID-19 for up to 12 months.

**Preliminary Serum Virus Neutralizing Titers After of a Single 300 mg IM Dose of ADG20**



*Combined Phase 2/3 STAMP Trial of ADG20 for the Treatment of COVID-19*

Emerging evidence has shown that for high-risk patients, intervention with a mAb therapy early in the course of infection can prevent disease progression, hospitalization and death. Based on this evidence, we are conducting our STAMP trial, a combined Phase 2/3 clinical trial of ADG20 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 to be a double-blind, randomized, placebo-controlled clinical trial comparing the efficacy of a single IM dose of ADG20 to placebo, with a target enrollment of approximately 1,100 patients, all of which will be enrolled outside of the United States. After evaluation of safety data from the Phase 2 portion of the trial, we may expand enrollment to adolescents and pregnant women in the Phase 3 portion. In addition, an independent data monitoring committee, or iDMC, meeting is anticipated in the fourth quarter of 2021 to evaluate futility at the Phase 2 to Phase 3 transition. The primary objectives of this clinical trial are to assess the safety and efficacy of ADG20 compared to placebo in the prevention of COVID-19-related hospitalization or death through Day 29.

We designed our STAMP trial to have a pre-specified interim analysis to support the potential to demonstrate early evidence of efficacy and to submit an EUA. If the interim analysis is positive and the public health emergency is still in effect, we plan to submit an EUA to the FDA. We anticipate that the interim analysis and subsequent EUA submission may occur as early as the first quarter of 2022. Our EUA submission will be based on clinical and virology endpoints and will be supplemented with non-clinical virological data demonstrating ADG20 activity against known SARS-CoV-2 variants of concern. Our EUA plan is supported by recently issued FDA guidance. If the Phase 3 data are positive, either at the interim analysis or at the completion of the trial, we expect to submit a biologics license application, or BLA, to the FDA as early as the second half of 2022 for full approval of ADG20 for the treatment of mild to moderate COVID-19 in patients at high risk of progressing to severe COVID-19 and/or hospitalization. Our BLA for the treatment indication will be further supported by clinical data from the EVADE trial.

In order to demonstrate clinical efficacy of ADG20 in patients where other mAb therapies are expected to have more limited success, we are prioritizing enrollment of the STAMP trial in countries with high rates of

## [Table of Contents](#)

SARS-CoV-2 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.

### *Combined Phase 2/3 EVADE Trial of ADG20 for the Prevention of COVID-19*

We have initiated our combined Phase 2/3 EVADE clinical trial of ADG20 to evaluate the safety and efficacy of ADG20 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, 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 population also includes 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 ADG20 in preventing COVID-19, with a target enrollment of approximately 6,400 individuals in the United States and other countries. The primary endpoint is the proportion of participants with laboratory-confirmed symptomatic COVID-19 through Day 28 for the post-exposure cohort and through six months for the pre-exposure cohort. In addition, we will follow participants for 12 months to assess the proportion of participants who develop symptomatic COVID-19 through this time period in both cohorts. For those participants who do get infected with SARS-CoV-2, we will evaluate the impact of ADG20 on viral load as a surrogate for transmission potential. After evaluation of data from the first 200 adult participants across both cohorts in the Phase 2 portion of the trial, we may expand enrollment to adolescents and pregnant women in the Phase 3 portion.

We initiated enrollment in our EVADE trial on April 27, 2021 and have completed enrollment of the planned 200 Phase 2 participants. The Phase 3 portion of the EVADE trial is ongoing with a planned iDMC meeting in the third quarter of 2021 to provide recommendations regarding inclusion of adolescents and pregnant and lactating women in the Phase 3 portion of the trial. As of July 28, 2021, over 400 participants have been randomized to the EVADE study. To date, two treatment-emergent serious adverse events have been reported. Both events were considered unrelated to study drug upon Investigator and Sponsor review. Because these events were assessed as unrelated to study drug, they remain blinded and are not subject to expedited reporting to the FDA.

Phase 3 data for the post-exposure cohort of EVADE are anticipated as early as the first half of 2022. If the Phase 3 data are positive in the post-exposure cohort, we plan to submit a BLA to the FDA as early as the second half of 2022 for both the treatment and post-exposure prophylaxis indications. An interim analysis of futility for the pre-exposure cohort is planned for the first half of 2022 with topline data anticipated as early as the second half of 2022. Assuming favorable results, we are planning to file a supplemental BLA in the first half of 2023 for this indication. Similar to our STAMP trial, we are prioritizing enrollment in countries, including the United States, with high rates of SARS-CoV-2 variants, including 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. We may not meet our time frames for submission, and if we do meet such timelines, there is no guarantee the FDA would approve our submission, or on the time frame we have indicated.

### *Pediatric Clinical Development Plan*

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. In addition, children of all ages are infectious and capable of transmission, regardless of symptom status, and the contribution of children to ongoing disease transmission is likely underappreciated. The secondary impacts of the COVID-19 pandemic on children due to widespread school closure, including a burgeoning mental health crisis, food insecurity and loss of gains in literacy, further attest to the need for safe and effective agents to prevent COVID-19 in children to support widespread school re-opening. Prevention efforts in children are also important for protection of high-risk adults who have contact with children and may

## [Table of Contents](#)

not be fully protected by vaccination, as well as for the achievement of global herd immunity given that 25% of the world's population are under the age of 14.

Similar to our strategy for the adult and adolescent populations, we anticipate generating data to support the use of ADG20 for both the treatment and prevention of COVID-19 in the pediatric population. We believe ADG20 has the potential to provide a treatment option for children at high risk of severe disease, a viable prevention option for children with household or other high-risk exposures and an alternative to vaccines for certain high-risk children. Based on decades of experience using Synagis, an antibody administered to high-risk infants and toddlers for the prevention of severe lower respiratory tract disease due to RSV, we believe the pediatric use of ADG20 could become well-accepted for certain subsets of the pediatric population.

### **Commercial Opportunity**

#### *Market Opportunity*

We believe that three core assumptions underpin the robust commercial opportunity inherent in ADG20 as both a treatment and preventative option for COVID-19:

- **Vaccines alone are not expected to adequately address the COVID-19 pandemic.** We believe high levels of vaccine hesitancy may leave as many as 100 million people in the United States and 2 billion people worldwide susceptible to COVID-19, assuming that less than 70% of the population will take a full course of a vaccine. We also believe there is a significant portion of the population that will choose not to receive the second vaccine dose or a potential future booster, which will make the duration of their protection uncertain. We also believe the challenges around the distribution and storage of certain vaccines will make widespread administration difficult in less developed or remote parts of the world. As a result, our epidemiological modeling has suggested that as much as 50% of the global population may be susceptible to infection within three years based on current assumptions of viral transmissibility as well as vaccine adoption, availability and length of protection, even when assuming that vaccine boosters are readily available. We believe these predictive assessments are indicative of the significant opportunity that may be available for a mAb therapy like ADG20 that has the potential to offer both treatment and preventative benefit.
- **ADG20 will find clinical application as both a complement to and supplement for vaccine use.** We conducted market research with physicians in the United States and Europe to better understand their perceptions of the potential profile of ADG20 and its likely applications. When shown the product profile of ADG20 versus four other mAbs in development, casirivimab/imdevimab (REGEN-COV), bamlanivimab/etesevimab (LY-CoV555/016), cilgavimab/tixagevimab (AZ7442) and sotrovimab (VIR-7831), both groups of physicians preferred ADG20 as a potential preventative for all types of individuals, including those unvaccinated, as well as a supplement for high-risk individuals, such as the elderly and the immunocompromised. For treatment, both groups of physicians also preferred ADG20 for all patient types, including low- and high-risk patients as well as pre-symptomatic, but infected, patients. We believe the results of our market research support the potential acceptance of ADG20 as both a complement to and supplement for vaccines across a wide variety of individuals.
- **ADG20 can both address COVID-19 and be a stockpiling product of choice for COVID-2X, the next SARS-like coronavirus.** We believe that the aggregate of ADG20's potential advantages, including its dosing convenience, the potential durability of its efficacy and its utility against SARS-CoV-2 variants, position ADG20 as a compelling option to address the current COVID-19 pandemic. In addition, ADG20's broad activity against a diverse group of SARS-related viruses make ADG20 an attractive option to enable stockpiling purchases to address future potential pandemics due to SARS-like viruses. To further enhance ADG20's stockpiling profile, we are developing a lyophilized formulation of the API of ADG20 to further extend the shelf life of the drug product under refrigerated conditions. Through a combination of the lyophilized form and the long-term frozen storage of the drug substance intermediate, we believe the shelf life can be even further extended.



### *Addressable Markets*

We have identified four distinct patient segments for those 12 years old and older, which represents approximately 285 million people in the United States. In April 2021, we conducted a market research analysis of 156 physicians in the United States and 236 physicians in Europe to understand their perspectives and preferences for the treatment and prevention of SARS-CoV-2 infection.

- **Treatment:** *Patients recently diagnosed with COVID-19.* In 2022 and beyond, we estimate that approximately 2.6% of the U.S. population 12 years old and older will be infected with SARS-CoV-2. This infection rate is consistent with the annual incidence of influenza, which, according to the CDC, on an annual basis is between 3% and 11% of the U.S. population. A SARS-CoV-2 infection rate of approximately 2.6% would result in approximately 7.4 million infected individuals annually in the United States, or approximately 20,000 cases per day. In our market research, 26% of U.S. physicians selected mAbs as their primary treatment choice for patients infected with SARS-CoV-2 who are at moderate risk and within seven days of diagnosis. For high-risk patients, 47% of U.S. physicians selected mAbs as their primary treatment choice.
- **Post-Exposure Prophylaxis:** *Non-vaccinated patients with close exposure to a SARS-CoV-2-infected patient.* Determining the number of people exposed by one infected person is difficult to estimate. As a proxy, we estimate that each infected person will expose at least one non-vaccinated person, on average. Therefore, the estimated 7.4 million infected patients would expose approximately 7.4 million non-vaccinated people annually. Our market research showed that 28% of U.S. physicians would recommend a mAb therapy for post-exposure prophylaxis compared to vaccines, antivirals, corticosteroids, other therapies or no therapy.
- **Vaccine Supplement:** *Patients seeking to supplement their vaccine protection against SARS-CoV-2 and/or who are deterred by potential booster doses due to vaccine side effects.* In our market research, U.S. physicians clearly indicated that they would consider using a combination of vaccines and a mAb therapy in a variety of patient types, including in 28% to 68% of moderate- to high-risk patients with medium exposure risk and 49% to 81% of moderate- to high-risk patients with high exposure risk. Additionally, patients who experienced side effects during their initial vaccine series may choose a mAb therapy instead of a vaccine booster for waning immunity or protection against potential variants. To estimate the size of this segment, we assume that approximately 65% of patients would be fully vaccinated by the end of 2022 and that these vaccines are approximately 80% effective, which yields a vaccine protection rate of approximately 52%. In the United States, we estimate that there will be more than 150 million people in this segment who are not already counted in other segments.
- **Pre-Exposure Prophylaxis:** *This group represents the remainder of the population (i.e., those that were not counted in the three patient segments described above).* In particular, this group includes non-vaccinated individuals as well certain vaccinated individuals for whom vaccines are likely to provide suboptimal protection, such as those who are immunocompromised. In the United States, we estimate that this segment includes approximately 120 million individuals, of whom approximately eight million are immunocompromised. Immunocompromised individuals are considered high risk, and in our market research, U.S. physicians indicated that they would consider using a mAb therapy or a combination of a vaccine and a mAb therapy in 45% to 87% of high-risk patients, depending on their exposure risk.

Although we believe that COVID-19 will be marked by variant-driven oscillating waves of infections, our addressable market estimates assume a stable endemic year over year.

### *ADG20 Attributes vs. Competitive mAbs*

We believe ADG20 has a unique combination of attributes that positions ADG20 to be a differentiated mAb for both the treatment and prevention of COVID-19.

**Low Risk of Clinical Resistance.** The currently known SARS-CoV-2 variants of concern 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. 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 variants of concern. For example, casirivimab, bamlanivimab, etesevimab and regandivimab all show significant loss of *in vitro* neutralizing potency against the Beta (B.1.351), Gamma (P.1), Iota (B.1.526) and/or Epsilon (B.1.429) variants, which contain mutations at the key amino acid residues recognized by these antibodies. Furthermore, the EUA for bamlanivimab was recently revoked by the FDA due to the increase in SARS-CoV-2 variants resistant to this antibody, raising concerns of increased risk of treatment failure and distribution of a second agent, bamlanivimab/etesevimab, has been paused in the United States due to data showing that the combined frequency of two variants resistant to this product, the Gamma (P.1) and Beta (B.1.351) variants, now exceeds 11% in the United States and is trending upward. In contrast, ADG20 binds to conserved residues that are not readily targeted by public antibodies. This suggests that these residues are less likely to mutate than those recognized by other antibodies, which is supported by preliminary data demonstrating that mutations in the ADG20 binding site are currently present at extremely low frequency in circulating SARS-CoV-2 viruses and none of the variants of concern described to date contain mutations in the ADG20 binding site. Thus, ADG20 demonstrates neutralizing activity *in vitro* against common circulating SARS-CoV-2 variants, including the Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1) and Delta (B.1.617.2) variants of concern and additional variants of interest.

**Half-Life Extension.** ADG20 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 ADG20 is supported by preliminary pharmacokinetic data from the Phase 1 healthy volunteer study. Other antibodies that do not include half-life extensions, such as casirivimab/imdevimab, bamlanivimab/etesevimab and regdanvimab, will likely require frequent periodic administration to provide an extended duration of protection.

**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, etesevimab and cilgavimab/tixagevimab include Fc modifications that reduce innate immune effector functions. In contrast, ADG20 was engineered to retain Fc-mediated innate immune effector activity, including ADCC and ADCP.

**Potency.** Our definition for potent *in vitro* neutralization of SARS-CoV-2 is demonstration of an *in vitro* IC<sub>50</sub> approximately equal to 0.01 mcg/mL or less against a range of authentic SARS-CoV-2 variants, including Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1) and Delta (B.1.617.2). Of the clinical-stage and authorized mAbs, only ADG20 and AZD1061 have this characteristic.

**Convenient Dosing Regimen.** Given the high potency, low viscosity and high concentration formulation of ADG20, we are developing ADG20 as a single-dose IM injection for both the treatment and prevention of COVID-19. To our knowledge, the dosing regimens for currently available or clinical-stage SARS-CoV-2 mAbs require either IV infusion or multiple subcutaneous or intramuscular injections for the treatment and/or prevention of COVID-19.

**Breadth.** ADG20 has demonstrated broad neutralizing activity against SARS-CoV-2 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 compared to ADG20.

## Table of Contents

### ADG20 Attributes vs. COVID Oral Antivirals

We believe ADG20 has several advantages over COVID oral antivirals in development for treatment and post-exposure prophylaxis settings. Oral antivirals require patients to take several doses over several days, whereas ADG20 has the potential to provide clinical benefit with a single IM injection in both the treatment and post-exposure prophylaxis settings. Oral antivirals require the patient to receive, fill and pay for the prescription via a retail or specialty pharmacy, whereas ADG20 is not expected to require a prescription if given in a physician's office, minimizing delays in administration of therapy.

### Go-to-Market Strategy

We believe the commercialization of ADG20 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 and Europe, where we believe a focused commercial infrastructure will be able to successfully commercialize ADG20. We have begun discussions with some of these entities and will continue to do so as we progress ADG20 through a potential EUA and commercialization. In other markets, such as Latin America, Asia-Pacific, including China, and Middle Eastern and African countries, we intend to commercialize ADG20 through partnerships.

### Additional Product Candidates Beyond ADG20

PROGRAM	PLATFORM	INDICATION(S)	DEVELOPMENT STATUS				
			DISCOVERY	IND-ENABLING	PHASE 1	PHASE 2	PHASE 3
<b>Coronaviruses</b>							
ADG20	mAb	Prevention	[Progress bar: ~90%]				
ADG20	mAb	Treatment	[Progress bar: ~75%]				
ADG10	mAb	Treatment/Prevention	[Progress bar: ~40%]				
Pan-CoV	Vaccine	Prevention	[Progress bar: ~20%]				
<b>Influenza</b>							
Multiple mAbs	mAb	Prevention	[Progress bar: ~10%]				

As illustrated in the graphic above, we are developing additional product candidates, such as ADG10, for potential use in combination with ADG20 for the treatment and prevention 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.

### Additional Broadly Neutralizing Antibodies in Development

We envision additional product development opportunities emerging from our development of ADG20 for the treatment and prevention of COVID-19. We are initiating IND-enabling studies with ADG10, an additional broadly neutralizing antibody for potential use in combination with ADG20 for COVID-19. We believe the incorporation of a second broadly neutralizing antibody that targets a distinct viral epitope from the epitope targeted by ADG20 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 arise from additional SARS-like viruses with pandemic potential. We anticipate submitting an IND to the FDA in early 2022. If cleared, we anticipate initiating first-in-human clinical development in the first quarter of 2022.

## Table of Contents

A number of *in vitro* studies, including assessments of binding affinity and neutralization potency, have been conducted with ADG10 and ADG1, the parent molecule of ADG10. ADG1 is an affinity-matured progeny of ADI-55689, an antibody that was isolated from a survivor of the 2003 SARS outbreak along with the parent molecule of ADG2/ADG20. Affinity maturation increased ADG1 binding affinity to the SARS-CoV-2 S protein and neutralization potency against SARS-CoV-2 by as much as 85-fold and 40-fold, respectively. ADG1 binds with high affinity to the RBD of the spike proteins of multiple ACE-2 targeting sarbecoviruses and has been shown to neutralize multiple members of this group of SARS-like viruses *in vitro*. To create ADG10, the same Fc region modification included in ADG20 that was designed to extend half-life was introduced into ADG1.

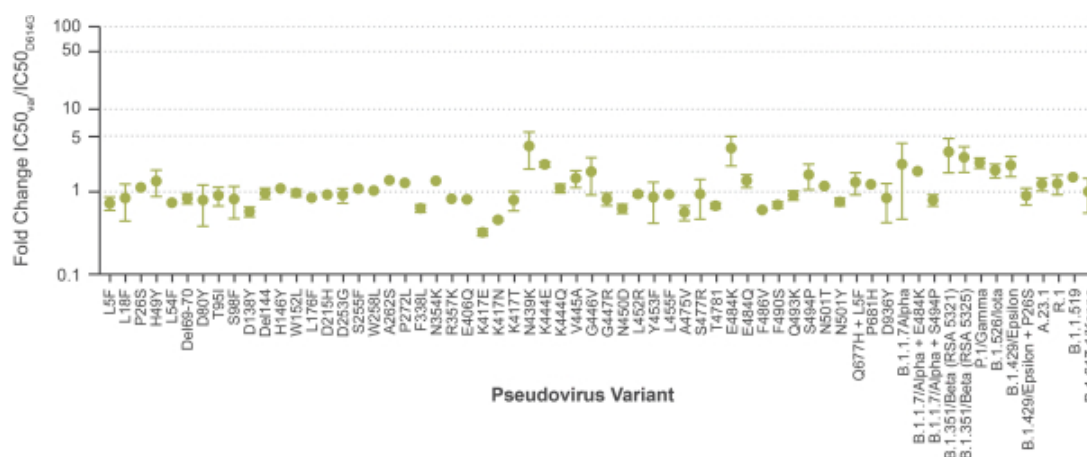
Similar to ADG2, ADG1 possesses broad activity and binds with high affinity to a diverse set of RBD molecules from naturally circulating SARS-CoV-2 variants and related sarbecoviruses. ADG10 has demonstrated broad neutralizing activity against authentic SARS-CoV-2 viruses, including the Victoria virus strain and the Alpha (B.1.1.7), Beta (B.1.351), Gamma (P.1) and Delta (B.1.617.2) variants. As shown in the table below, ADG10 neutralized all five viruses tested, as demonstrated by the low IC<sub>50</sub> values and 100% neutralization plateaus achieved.

### ADG10 Displays Neutralizing Activity Against SARS-CoV-2 Variants of Concern

	IC <sub>50</sub> (mcg/mL)				Neutralization Plateau (%)					
	Victoria	Alpha B.1.1.7	Beta B.1.351	Gamma P.1	Delta B.1.617.2	Victoria	Alpha B.1.1.7	Beta B.1.351	Gamma P.1	Delta B.1.617.2
<b>ADG10</b>	0.006	0.010	0.011	0.003	0.026	100	100	100	100	100

The neutralization potency and breadth of ADG10 was further evaluated against a panel of 64 SARS-CoV-2 pseudovirus variants incorporating single or double amino acid spike substitutions or spike proteins encoding the full sets of mutations observed in emerging variants of concern and variants of interest, including the Epsilon (B.1.427/429), Iota (B.1.526) and Kappa (B.1.617.1) variants. We utilized the non-clinical and pre-clinical services program offered by the National Institute of Allergy and Infectious Disease to generate these data. Similar to ADG20, ADG10 maintained neutralization activity across all variants tested with IC<sub>50</sub> values within approximately 0.3- to 4-fold relative to the D614G reference strain, as shown in the graphic below.

### ADG10 Displayed Neutralization Activity Against a Broad Panel of SARS-CoV-2 Variants



### **Additional Programs in Discovery**

We believe that the robust antibody discovery and development capabilities that have enabled our expedited advancement of ADG20 into clinical trials may also be used to develop therapeutic or preventative options for other respiratory viral infections, such as seasonal and pandemic influenza. Broadly neutralizing antibodies with extended half-life have the potential to be used directly for the prevention of respiratory viral infection and disease.

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 ADG10, ADG20 and other broadly neutralizing antibodies discovered by us and others. 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.

### **Manufacturing Strategy**

We do not currently own or operate any manufacturing facilities and have invested significant resources to develop and scale up a suitable manufacturing process for ADG20 in partnership with a contract manufacturer, WuXi, with whom we have been working since our inception. With WuXi, we have developed a high yield, industry standard mAb drug substance manufacturing process suitable for large-scale manufacturing, as well as an industry standard sterile liquid drug product manufacturing process and formulation that enables IM delivery of ADG20. Currently, the ADG20 drug substance is produced using a recombinant Chinese Hamster Ovary, or CHO, commercial cell line, fed-batch suspension cell culture and a chromatography column-based purification process. ADG20 drug substance has been successfully manufactured at commercial scale and with acceptable yields in the planned launch facility at WuXi. We plan to implement the industry standard sterile liquid drug product manufacturing process in a WuXi commercial facility prior to the submission of our EUA application.

We have established long-term master services agreements with WuXi, pursuant to which we purchase drug substance for both clinical and commercial supply. We may terminate the master services agreements at any time for convenience in accordance with the terms of the agreements, including fulfilling our obligation to make full payment for 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 license agreement with WuXi that allows for the transfer and use of the commercial cell line currently used in the manufacture of ADG20 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 license, 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.

While we expect to continue to devote significant resources to the process development and optimization of the manufacture of ADG20 and its scale up, we believe the manufacturing processes for mAbs such as ADG20 are well established and should not create meaningful impediments to either clinical development or commercial launch. However, within the context of the global pandemic, sufficient capacity for commercial scale manufacturing has been constrained on a worldwide basis. We continue to identify additional drug substance and drug product contract manufacturers to ensure that we will have sufficient capacity as well as redundancy within our supply chain to avoid product shortages in the future. We are actively pursuing a second source contract manufacturer to add capacity and redundancy and to meet anticipated demand, if ADG20 is authorized or approved. While any reduction or halt in the supply of drug substance or drug product could limit our ability to

## [Table of Contents](#)

develop our product candidates until a replacement contract manufacturer is found and qualified, we believe that we have sufficient clinical supply of ADG20 to support our current and planned clinical trials and to fulfill our initial commercial launch needs upon either receipt of an EUA or BLA approval. We will also continue to apply mitigation strategies to ensure minimal disruption to our manufacturing supply due to global raw material supply chain shortages.

### **Our Relationship with Adimab**

We were founded in June 2020 by Adimab to focus initially on the development of antibodies for both the treatment and prevention 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. Since its founding in 2007, Adimab has partnered with over 80 pharmaceutical and biotechnology companies, including Biogen, GlaxoSmithKline, Merck, Regeneron and Takeda, and the Adimab platform has been used in more than 385 antibody discovery and optimization programs, more than 40 of which have advanced into clinical trials, including five programs in pivotal clinical trials. Five percent of all antibodies that entered clinical trials in 2020 originated from Adimab technology. Adimab has extensive domain expertise in B-cell immunology, and its prior discovery initiatives include targeting viral infections such as Ebola, Zika, RSV, hantavirus and yellow fever. We are leveraging this expertise to expedite our discovery and development activities and anticipate continued interaction with Adimab related to antibody discovery services.

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 ADG20. 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**

#### *Assignment and License Agreement with Adimab*

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,

## Table of Contents

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 August 2, 2021, we had made aggregate milestone payments of \$3.5 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 August 2, 2021, we had made aggregate payments of \$4.5 million to Adimab under the Adimab Assignment Agreement, inclusive of the milestone payments.

### ***Collaboration Agreement with Adimab***

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.



## **Table of Contents**

We are obligated to pay Adimab a quarterly fee of \$1.3 million, 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. 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 August 2, 2021, we had made no payments to Adimab under the Adimab Collaboration Agreement.

### ***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 ADG20. As part of the agreement, Biocon will be granted access to the data from our ongoing Phase 2/3 ADG20 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, Bii Biosciences Limited, Celltrion Healthcare Co, Ltd., Eli Lilly and Co, Regeneron Pharmaceuticals, Inc., Sab Biotherapeutics, Inc. and Vir Biotechnology, Inc. in collaboration with GlaxoSmithKline. In addition, we may face competition from many established pharmaceutical companies focused on developing oral antivirals for the treatment of COVID-19. 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 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 for commercially important technology, 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

## [Table of Contents](#)

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. Although we own a number of pending patent applications that have not yet issued as patents, we do not own or license any issued patents with claims directed to our product candidates, including ADG20, and we may not be successful in prosecuting our filed patent applications or obtaining patent protection for our product candidates. 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 field of cell therapy 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 cell therapy 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.

### ***ADG20 and ADG10***

As of August 2, 2021, we own one patent family for which we have filed one PCT patent application, one 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 and ADG10, 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 2041, without taking into account any possible patent term adjustment or extension.

As of August 2, 2021, we own two 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 ADG20 clinical trials and includes four U.S. provisional patent applications. The second patent family is directed to additional broadly neutralizing anti-coronavirus antibodies, combination therapies, and uses thereof and includes four 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.

### ***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

## [Table of Contents](#)

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;

## Table of Contents

- 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

## **Table of Contents**

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](http://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,

## Table of Contents

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

## Table of Contents

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.

### ***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



## Table of Contents

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



## [Table of Contents](#)

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

## Table of Contents

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 exists as to obtaining and maintaining coverage and adequate reimbursement for our product candidates, including ADG20, 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

## Table of Contents

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 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) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse-midwives; 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

## [Table of Contents](#)

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 litigation extended the 2% reduction, on average, to 2030 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, 2021. 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 new administration under President Biden 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, which began on February 15, 2021 and will remain 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 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 December 14, 2018, the U.S. District Court for the Northern District of Texas ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. On December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit held that the individual mandate is unconstitutional and remanded the case to the District Court to reconsider its earlier invalidation of the entire ACA. An appeal was taken to the U.S. Supreme Court, which heard oral arguments in the case on November 10, 2020. A ruling is expected in 2021. On February 10, 2021, the Biden administration withdrew the federal government's support for overturning the ACA. It is unclear how the

## [Table of Contents](#)

Supreme Court ruling, other such litigation 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. Recently, 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 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 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.

### **Employees and Human Capital Resources**

As of August 2, 2021, we had 74 full-time employees and one part-time employee. Of our 75 full- and part-time employees, approximately 23 have Ph.D. or M.D. degrees and 54 are engaged in research and development activities. We have a remote workforce, with approximately 43% of our employees based in Massachusetts, 16% based in California, 8% based in New Jersey, and the remaining 33% 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



---

## [Table of Contents](#)

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 a short-term office space building in Waltham, Massachusetts for general and administrative purposes. We do not own or lease any laboratory or manufacturing facilities, and we plan to enter into a lease for office space in the near term. 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.

### **Legal Proceedings**

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



## MANAGEMENT

### Executive Officers and Directors

The following table provides information regarding our current executive officers and directors, including their ages as of August 2, 2021:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
<b>Executive Officers</b>		
Tillman U. Gerngross, Ph.D.	57	Co-Founder, Chief Executive Officer and Director
Lynn Connolly, M.D., Ph.D.	54	Chief Medical Officer
Rebecca Dabora, Ph.D.	62	Chief Technology & Manufacturing Officer
Jane Pritchett Henderson	56	Chief Financial Officer
David Hering	47	Chief Operating Officer
Elham (Ellie) Hershberger, Pharm. D.	53	Chief Development Officer
<b>Key Employees</b>		
Laura Walker, Ph.D.	36	Co-Founder & Chief Scientific Officer
Eric Kimble, M.B.A.	54	Chief Commercial Officer
<b>Non-Employee Directors</b>		
René Russo, Pharm. D.	46	Co-Founder, Director and Chair of the Board
Terrance McGuire	65	Director
Ajay Royan	41	Director
Howard Mayer, M.D.	58	Director
Anand Shah, M.D.	41	Director
Tom Heyman	65	Director
Michael Wyzga	66	Director

### Executive Officers

**Tillman U. Gerngross, Ph.D.** is our co-founder and has served as a member of our board of directors and as our Chief Executive Officer since June 2020. Dr. Gerngross is a founder, director and executive officer of numerous biotechnology companies. He is a co-founder of Adimab, LLC and has served as its Chief Executive Officer and as a director since 2007. He is also a co-founder and Chairman of Avitide, Inc. since August 2012, a co-founder and Chairman of Alector, Inc. since September 2017, a co-founder, President and Chairman of Amagma, Inc. since August 2019 and a co-founder, President and Chairman of Ankyra Therapeutics, Inc. since November 2019. Dr. Gerngross is currently a Venture Partner at SV Life Sciences Advisors, LLC, which he joined in 2006. Dr. Gerngross co-founded GlycoFi, Inc. and served as its Chief Scientific Officer from 2000 to 2006 until it was acquired by Merck & Company, Inc. Dr. Gerngross currently teaches at the Thayer School of Engineering, at Dartmouth College, where he has taught since 1998. Dr. Gerngross received a B.S. and M.S. in Chemical Engineering and a Ph.D. in Molecular Biology from Technical University of Vienna. We believe Dr. Gerngross is qualified to serve as a member of our board of directors because of his knowledge of Adagio as a co-founder and his expertise as an executive officer and director in the biotechnology industry.

**Lynn Connolly, M.D., Ph.D.** has served as our Chief Medical Officer since July 2020. Prior to joining Adagio, Dr. Connolly served as Senior Vice President, Clinical Research from March 2020 to July 2020 and Vice President, Clinical Research from March 2018 to February 2020 of Vir Biotechnology, Inc. Dr. Connolly served as Vice President and Head of Late Development from January 2017 to March 2018 and Senior Medical

## [Table of Contents](#)

Director from January 2016 to January 2017 of Achaogen, Inc. Dr. Connolly received a B.A. in Molecular Biology from University of California, Berkeley and a M.D. and Ph.D. in Cell Biology from University of California, San Francisco.

**Rebecca Dabora, Ph.D.** has served as our Chief Technology & Manufacturing Officer since July 2020. In addition, Dr. Dabora is currently serving as Principal for RDBio Consulting LLC since July 2005. Prior to joining Adagio, Dr. Dabora served as Interim Chief Technology Officer of SwanBio Therapeutics, Inc. from July 2019 to July 2020 and Chief Technology Officer of Aspyrian Therapeutics, Inc. from March 2016 to March 2017. Dr. Dabora received a B.A. in Biochemistry from Bowdoin College and a Ph.D. in Applied Biological Sciences and Biochemical Engineering from the Massachusetts Institute of Technology.

**Jane Pritchett Henderson** has served as our Chief Financial Officer since December 2020. In addition, Ms. Henderson serves as a director and chair of the audit committee of Akero Therapeutics, Inc. since April 2019, of IVERIC bio, Inc. since January 2018 and of Sesen Bio, Inc., formerly Eleven Biotherapeutics, Inc., since October 2013. Prior to joining Adagio, Ms. Henderson served as Chief Financial Officer of Turnstone Biologics from June 2018 to December 2020, Chief Financial Officer and Senior Vice President, Corporate Development of Voyager Therapeutics, Inc. from January 2017 to June 2018 and Senior Vice President and Chief Financial & Business Officer of Kolltan Pharmaceuticals, Inc. from February 2013 to November 2016. Ms. Henderson received a B.S. in Psychology from Duke University.

**David Hering, M.B.A.** has served as our Chief Operating Officer since June 2021. Prior to joining Adagio, Mr. Hering served as the Head of the mRNA Global Franchise Business of Pfizer, Inc. from April 2021 to June 2021, the President of North America Vaccines of Pfizer, Inc. from December 2018 to April 2021 and the Vaccines Commercial Officer of Pfizer, Inc. from June 2015 to December 2018. Before joining Pfizer in 2015, Mr. Hering spent seven years at Novartis Vaccines, where he held the position of Head of the North America Region. Mr. Hering received an M.B.A. from Harvard Business School and a B.S. in Operations Research and Industrial Engineering from Cornell University.

**Elham (Ellie) Hershberger, Pharm.D.** has served as our Chief Development Officer since June 2020. Prior to joining Adagio, Dr. Hershberger served as President of EMH Consulting Group, Inc. from July 2017 to October 2020 and as Head of Clinical Development of Visterra, Inc. from January 2016 to July 2017. Dr. Hershberger received a B.S. in Chemistry from University of Minnesota and a Pharm.D. from Ferris State University.

### **Key Employees**

**Laura Walker, Ph.D.** is our co-founder and has served as our Chief Scientific Officer since June 2020. In addition, Dr. Walker has served in various roles at Adimab, LLC, including Group Leader, since May 2012 and has served as Senior Director of Antibody Sciences since October 2019. Dr. Walker received a B.S. in Biochemistry from University of Wisconsin-Madison and a Ph.D. in Microbiology and Immunology from The Scripps Research Institute.

**Eric Kimble, M.B.A.** has served as Chief Commercial Officer since September 2020. Prior to joining Adagio, Mr. Kimble served as Chief Commercial Officer for Entasis Therapeutics, Inc. from April 2019 to September 2020 and as a consultant for various emerging biotechnology companies from June 2013 to April 2019. Mr. Kimble received an A.B. in English Literature and Business Economics from Brown University and an M.B.A. from the Harvard Business School.

### **Non-Employee Directors**

**René Russo, Pharm.D.** is our co-founder and has served as the chair of our board of directors since October 2020. Dr. Russo has served as the Chief Executive Officer of Xilio Therapeutics, Inc since May 2019. Prior to her position at Xilio, Dr. Russo served as President and Chief Executive Officer of Arsanis, Inc. from April 2016

## Table of Contents

to November 2018, and as its Chief Development Officer from July 2015 to April 2016. In addition, Dr. Russo has served as a director of Celsius Therapeutics, Inc. since May 2020 and X4 Pharmaceuticals, Inc. since March 2019. Dr. Russo received a B.S. in Pharmacy and a Pharm.D. from Rutgers University. We believe Dr. Russo is qualified to serve as a member of our board of directors because of her experience as an executive at public and private pharmaceutical companies and her expertise in clinical development and commercialization of therapeutics.

**Terrance McGuire** has served as a member of our board of directors since October 2020. Mr. McGuire is a Founding Partner of Polaris Partners, a venture capital firm investing in technology and healthcare companies, since 1996. In addition, Mr. McGuire serves as chairman of the board of directors of Ironwood Pharmaceuticals, Inc. and has served as a director since 1998. Mr. McGuire also currently serves on the boards of directors of Acceleron Pharma, Inc. since 2005, Pulmatrix, Inc. since May 2016 and Adimab, LLC since August 2007. Mr. McGuire received a B.S. in physics and economics from Hobart College, an M.B.A. from Harvard Business School and an M.S. in Engineering from the Thayer School at Dartmouth College. We believe Mr. McGuire is qualified to serve as a member of our board of directors because of his expertise in the biotechnology industry through his career in venture capital as well as his experience as a director of several biotechnology companies.

**Ajay Royan** has served as a member of our board of directors since October 2020. Mr. Royan has served as Managing General Partner and Founder of Mithril Capital Management LLC, a venture capital firm investing in technology companies, since June 2012 and on the board of directors of several private companies in which Mithril Capital Management LLC or its affiliates have invested. In addition, Mr. Royan has served as a director of Adimab, LLC since September 2014 and has served as a director of Blacksky Holdings, Inc. since June 2016. Mr. Royan serves on the Science Advisory Board of the Oak Ridge National Laboratory, the board of directors of Fulbright Canada, and the Presidents' Circle of the National Academies of Science, Engineering, and Medicine. Mr. Royan received a B.A. from Yale University. We believe Mr. Royan is qualified to serve as a member of our board of directors because of his expertise in the technology industry through his career in venture capital and his experience as a director of several technology companies.

**Howard Mayer, M.D.** has served as a member of our board of directors since August 2020. In addition, Dr. Mayer has served on the board of directors of Entasis Therapeutics Holdings Inc. since August 2019. Dr. Mayer has served as the Executive Vice President, Head of Research and Development for Ipsen Biopharmaceuticals, Inc. since December 2019. Prior to joining Ipsen, Dr. Mayer served as the Senior Vice President, Chief Medical Officer and Global Head of Research & Development, Neuroscience Division at Shire Pharmaceuticals, Inc., or Shire, from April 2018 to November 2019 until it was acquired by Takeda Pharmaceutical Company in 2019. Prior to that position, Dr. Mayer served as a Senior Vice President and Head of Global Research and Development at Shire from August 2017 to January 2018, and as a Senior Vice President and Head of Global Clinical Development at Shire from August 2013 to August 2017. Dr. Mayer received a B.A. from the University of Pennsylvania and an M.D. from Albert Einstein College of Medicine. We believe that Dr. Mayer is qualified to serve as a member of our board of directors because of his extensive experience in the biopharmaceutical industry and his scientific background.

**Anand Shah, M.D.** has served as a member of our board of directors since June 2021. Dr. Shah served as the Deputy Commissioner for Medical and Scientific Affairs at the U.S. Food and Drug Administration from January 2020 to January 2021. Dr. Shah has served as a senior advisor to Morgan Stanley since January 2021. Dr. Shah previously served as Chief Medical Officer of the Center for Medicare and Medicaid Innovation from October 2017 to January 2019 and Senior Medical Advisor from January 2019 to January 2020, both at the Centers for Medicare and Medicaid Services. Dr. Shah served as an Adjunct Senior Fellow at the Leonard David Institute of Health Economics at the University of Pennsylvania from March 2017 to January 2020. Dr. Shah received an M.D. from University of Pennsylvania, an M.P.H. in Health Care Management and Policy from the Harvard School of Public Health and a B.S. in Economics from Duke University. We believe Dr. Shah is qualified to serve as a member of our board of directors because of his expertise in health policy, the biotechnology field and bringing new technologies to market.

## [Table of Contents](#)

**Tom Heyman** has served as a member of our board of directors since June 2021. Mr. Heyman previously served as the President of Johnson & Johnson's Corporate Venture Capital Group from April 2015 to September 2019 and as the Global Head of Business Development for Johnson & Johnson's Pharmaceutical Group from March 1992 to March 2015. In addition, Mr. Heyman previously served as Chief Executive Officer of Janssen Pharmaceuticals from November 2008 to November 2016. Mr. Heyman has served as a director of OptiNose, Inc. since December 2020 and a director of Akero Therapeutics, Inc. since June 2020. Mr. Heyman received his Master of Laws from Katholieke Universiteit Leuven. We believe Mr. Heyman is qualified to serve as a member of our board of directors because of his expertise in the biotechnology industry through his career in venture capital.

**Michael Wyzga** has served as a member of our board of directors since July 2021. Mr. Wyzga currently serves as the President of MSW Consulting, Inc. since November 2013. Mr. Wyzga also currently serves as a member and chair of the board of directors for GenSight Biologics S.A. since July 2015 and for X4 Pharmaceuticals, Inc. since July 2018. Mr. Wyzga also currently serves as a member of the board and chair of the audit committee for LogicBio Therapeutics since December 2018 and for Exact Science, Inc. since February 2015. Mr. Wyzga serves as a member and deputy chair of the board of Mereo Pharmaceuticals since April 2019 and prior to that, Mr. Wyzga served as a member of the board of directors of OncoMed from October 2013 to April 2019. Mr. Wyzga received an M.B.A. from Providence College and a B.S. from Suffolk University. We believe Mr. Wyzga is qualified to serve as a member of our board of directors because of his experience in the biotechnology space and his financial experience.

### **Board Composition**

Our business and affairs are managed under the direction of our board of directors, which currently consists of six members. Our directors were elected to, and currently serve on, the board pursuant to a voting agreement among us and all of our stockholders and voting rights granted by our current amended and restated certificate of incorporation. The voting agreement will terminate upon the closing of this offering, after which there will be no further contractual obligations regarding the election of our directors.

In accordance with our amended and restated certificate of incorporation and amended and restated bylaws that will be in effect upon the closing of this offering, our board of directors will be divided into three classes, each of which will consist, as nearly as possible, of one-third of the total number of directors constituting our entire board and which will serve staggered three-year terms. At each annual meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Our directors will be divided among the three classes as follows:

- Class I, which will consist of Dr. Russo and Mr. Royan, and their terms will expire at our first annual meeting of stockholders to be held after the closing of this offering;
- Class II, which will consist of Messrs. Heyman and McGuire and Dr. Mayer, and their terms will expire at our second annual meeting of stockholders to be held after the closing of this offering; and
- Class III, which will consist of Drs. Gerngross and Shah and Mr. Wyzga, and their terms will expire at our third annual meeting of stockholders to be held after the closing of this offering.

Our amended and restated bylaws, which will become effective upon the closing of this offering, will provide that the authorized number of directors may be changed only by resolution approved by a majority of our board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change of control.

### **Director Independence**

Applicable Nasdaq rules, or the Nasdaq Listing Rules, require a majority of a listed company's board of directors to be composed of independent directors within one year of listing. In addition, the Nasdaq Listing

## Table of Contents

Rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act of 1934, as amended, or the Exchange Act. The Nasdaq independence definition includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees, that neither the director nor any of his family members has engaged in various types of business dealings with us and that the director is not associated with the holders of more than 5% of our common stock. In addition, under applicable Nasdaq rules, a director will only qualify as an "independent director" if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

Our board of directors has determined that all of our directors other than Dr. Gerngross and Messrs. McGuire and Royan, representing three of our eight directors, are "independent directors" as defined under applicable Nasdaq rules. In making such determination, our board of directors considered the current and prior relationships that each such director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each director and the transactions described in the section titled "Certain Relationships and Related Party Transactions."

There are no family relationships among any of our directors or executive officers.

### **Role of the Board in Risk Oversight**

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure. Following the completion of this offering, we intend for our audit committee to have the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee will also monitor compliance with legal and regulatory requirements.

### **Board Committees**

Our board of directors has established an audit committee, compensation committee and a nominating and corporate governance committee, each of which operate pursuant to a committee charter. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below.

#### ***Audit Committee***

Upon the completion of this offering, our audit committee will consist of Dr. Russo and Messrs. Heyman and Wyzga, with Mr. Wyzga serving as chair of the audit committee. Our board of directors has determined that each of these individuals meets the independence requirements of Rule 10A-3 under the Securities Exchange Act of 1934, or the Exchange Act, and the applicable listing standards of Nasdaq. Each member of our audit committee can read and understand fundamental financial statements in accordance with Nasdaq audit committee requirements. Our board of directors has also determined that Mr. Wyzga qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In arriving at these determinations, the board has examined each audit committee member's scope of experience and the nature of their prior and/or current employment.

The functions of this committee include, among other things:

- helping our board of directors oversee our corporate accounting and financial reporting processes;

## Table of Contents

- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;
- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviewing related person transactions;
- obtaining and reviewing a report by the independent registered public accounting firm at least annually that describes our internal quality control procedures, any material issues with such procedures and any steps taken to deal with such issues when required by applicable law; and
- approving or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

We believe that the composition and functioning of our audit committee will comply with all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

### ***Compensation Committee***

Upon the completion of this offering, our compensation committee will consist of Drs. Mayer and Shah and Mr. Wyzga, with Dr. Mayer serving as chair of the compensation committee. Each of these individuals is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act. Our board of directors has determined that each of these individuals is “independent” as defined under the applicable listing standards of Nasdaq, including the standards specific to members of a compensation committee. The functions of this committee include, among other things:

- reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;
- making recommendations to the full board of directors regarding the compensation and other terms of employment of our executive officers;
- reviewing and making recommendations to the full board of directors regarding performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;
- reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;
- reviewing and making recommendations to the full board of directors regarding the type and amount of compensation to be paid or awarded to our non-employee board members;
- establishing policies with respect to votes by our stockholders to approve executive compensation to the extent required by Section 14A of the Exchange Act and, if applicable, determining our recommendations regarding the frequency of advisory votes on executive compensation;
- reviewing and assessing the independence of compensation consultants, legal counsel and other advisors as required by Section 10C of the Exchange Act;
- administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;

## Table of Contents

- reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;
- reviewing and making recommendations to the full board of directors regarding the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;
- reviewing with management and approving our disclosures under the caption “Compensation Discussion and Analysis” in our periodic reports or proxy statements to be filed with the SEC, to the extent such caption is included in any such report or proxy statement;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and evaluating on an annual basis the performance of the compensation committee and the compensation committee charter.

We believe that the composition and functioning of our compensation committee will comply with all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

### ***Nominating and Corporate Governance Committee***

Upon the completion of this offering, our nominating and corporate governance committee will consist of Mr. Heyman and Drs. Mayer and Shah, with Mr. Heyman serving as chair of the nominating and corporate governance committee. Our board of directors has determined that each of these individuals is “independent” as defined under the applicable listing standards of Nasdaq and SEC rules and regulations. The functions of this committee include, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles and recommending to our board of directors any changes to such policies and principles;
- reviewing and making recommendations to the board of directors with respect to management succession planning;
- considering questions of possible conflicts of interest of directors as such questions arise; and
- reviewing and evaluating on an annual basis the performance of the nominating and corporate governance committee and the nominating and corporate governance committee charter.

We believe that the composition and functioning of our nominating and corporate governance committee will comply with all applicable SEC and Nasdaq rules and regulations. We intend to comply with future requirements to the extent they become applicable to us.

### **Compensation Committee Interlocks and Insider Participation**

None of our directors who serve as a member of our compensation committee is, or has at any time during the past year been, one of our officers or employees. None of our executive officers currently serves, or in the past year has served, as a member of the board of directors or compensation committee of any other entity that has one or more executive officers serving on our board of directors or compensation committee.



## [Table of Contents](#)

### Code of Business Conduct and Ethics

Effective upon the closing of this offering, we will adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. Following the closing of this offering, the full text of the Code of Conduct will be available on our website at [adagiotx.com](http://adagiotx.com). We intend to post on our website all disclosures that are required by law or the listing standards of the Nasdaq Global Market concerning any amendments to, or waivers from, any provision of the Code of Conduct. Information contained on, or that can be accessed through, our website is not incorporated by reference into this prospectus. We have included our website in this prospectus solely as an inactive textual reference.

### Non-Employee Director Compensation

With the exception of the payments provided pursuant the independent director compensation policy adopted in the fourth quarter of 2020, as described below, we have not historically paid cash retainers or other compensation with respect to service on our board of directors, except for reimbursement of direct expenses incurred in connection with attending meetings of the board or committees.

In October 2020, we adopted an independent director compensation policy pursuant to which our independent directors are entitled to receive an annual cash retainer of \$35,000 for serving on our board of directors, payable in arrears on a quarterly basis. In addition, each independent director who is appointed or elected following the policy's adoption will be entitled to be granted an option to purchase 0.25% of our outstanding shares issuable at the start of the director's term at an exercise price equal to the fair market value of our common stock on the date of grant, with 25% of the underlying shares vesting on the first anniversary of the grant date and the remainder vesting in 36 equal monthly installments thereafter, subject to the director's continued service through the applicable vesting date. While Dr. Russo and Dr. Howard Mayer are both independent directors, only Dr. Mayer has received compensation pursuant to this policy because Dr. Russo received compensation pursuant to the consulting agreement described below and received an option award as a co-founder of the Company.

We have adopted a non-employee director compensation policy that became effective upon the effective date of the registration statement of which this prospectus forms a part, pursuant to which each of our non-employee directors will be eligible to receive compensation for service on our board of directors and committees of our board of directors.

#### 2020 Director Compensation Table

The following table sets forth information regarding the compensation earned for service on our board of directors in 2020 by our non-employee directors. Tillman U. Gerngross, Ph.D., our Chief Executive Officer, is also a member of our board of directors but did not receive any additional compensation for service as a director.

<u>Name</u>	<u>Fees Earned or Paid in Cash (\$)</u>	<u>Option Awards (\$)(1)(2)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
René Russo, Pharm.D.	78,343 (3)	5,941	—	84,284
Terrance McGuire	—	—	—	—
Ajay Royan	—	—	—	—
Philip Chase	—	—	—	—
Howard Mayer, M.D.	14,138	—	—	14,138
Anand Shah, M.D.	—	—	—	—
Tom Heyman	—	—	—	—
Michael Wyzga	—	—	—	—



## Table of Contents

- (1) The amounts disclosed represent the aggregate grant-date fair value of the stock options granted under our 2020 Plan, computed in accordance with ASC Topic 718. The assumptions used in calculating the grant-date fair value of the stock options are set forth in the notes to our audited consolidated financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the non-employee director upon vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.
- (2) Dr. Russo's consulting agreement (referred to below) acknowledges that, in consideration of her consulting services, she was granted an option to purchase 1,985,295 shares of our common stock, which option vests as to 25% of the underlying share on June 15, 2021, and the remainder of the underlying shares vest in 36 substantially equal monthly installments, subject to her continued service through each vesting date. The terms of Dr. Russo's option also include the ability for Dr. Russo to exercise the option in full on the date of grant. Dr. Russo exercised her stock option prior to December 31, 2020 and received unvested shares of our common stock. In the event of a "change in control" (as defined our 2020 Plan), the vesting of Dr. Russo's option will accelerate in full, subject to her continued service as of immediately prior to such change in control. Such shares are subject to a right of repurchase in favor of us at the original option exercise price that lapses in accordance with such vesting schedule. As a result, none of our non-employee directors held option awards as of December 31, 2020, and none of our non-employee directors held stock awards as of December 31, 2020, other than Dr. Russo.
- (3) This amount represents cash consulting fees paid during 2020 pursuant to Dr. Russo's consulting agreement with us, as described below.

### ***Non-Employee Director Compensation Policy***

In anticipation of this offering and the increased responsibilities of our directors as directors of a public company, our board of directors has adopted a non-employee director compensation policy, which became effective on the effective date of the registration statement of which this prospectus forms a part, pursuant to which each of our directors who is not an employee or consultant of our company will be eligible to receive compensation for service on our board of directors and committees of our board of directors.

Each eligible director will receive an annual cash retainer of \$40,000 for serving on our board of directors and the independent chairperson of the board of directors will receive an additional annual cash retainer of \$30,000 for his or her service. The chairperson of the audit committee will be entitled to an additional annual cash retainer of \$15,000, the chairperson of the compensation committee will be entitled to an additional annual cash retainer of \$10,000 and the chairperson of the nominating and corporate governance committee will be entitled to an additional annual cash retainer of \$8,000. The members of the audit committee will be entitled to an additional annual cash retainer of \$7,500, the members of the compensation committee will be entitled to an additional annual cash retainer of \$5,000 and the members of the nominating and corporate governance committee will be entitled to an additional annual cash retainer of \$4,000; however, in each case such cash retainer is payable only to members who are not the chairperson of such committee. All annual cash compensation amounts will be payable in equal quarterly installments in arrears, on the last day of each fiscal quarter in which the service occurred, pro-rated for any partial service in the applicable fiscal quarter.

Each new eligible director who joins our board of directors after this offering will be granted a non-statutory stock option to purchase a number of shares of our common stock with an aggregate Black-Scholes grant-date fair value of \$800,000 under our 2021 Plan, provided that in no event shall the number of shares granted exceed 150,000 shares. The shares subject to this grant will vest over a three-year period, with one-third of the shares vesting on the first anniversary of the grant date, and 1/36<sup>th</sup> of the shares vesting in equal monthly installments thereafter, subject to continued service as a director through each such vesting date.

On the date of each annual meeting of our stockholders, each eligible director who continues to serve as a director of our company following the meeting will be granted a non-statutory stock option to purchase shares of our common stock with an aggregate Black-Scholes grant-date fair value of \$400,000 under our 2021 Plan,

## Table of Contents

provided that in no event shall the number of shares granted exceed 75,000 shares. Following the effective date, if an eligible director joins our board of directors on a date other than the date of our annual stockholder meeting, upon the first annual stockholder meeting following such eligible director's appointment or election to the board of directors, such eligible director's annual grant will be pro-rated to reflect the time between the eligible director's appointment or election date and the date of such first annual stockholder meeting. The shares shall vest in full on the earlier of the first anniversary of the grant date or the date of the next annual stockholder meeting, subject to continued service as a director through such vesting date.

Each option awarded to eligible directors under the non-employee director compensation policy will be subject to accelerated vesting upon a Change in Control (as defined in the 2021 Plan).

The exercise price per share of each stock option granted under the non-employee director compensation policy will be equal to the closing price of our common stock on the Nasdaq Global Market on the date of grant. Each stock option will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of the eligible director's continuous service with us.

In addition, we 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.

### ***IPO Grants***

On the effective date of the registration statement of which this prospectus forms a part, each eligible director serving on our board of directors as of June 15, 2021 was granted a non-statutory stock option to purchase a number of shares of our common stock with an aggregate Black-Scholes grant-date fair value of \$400,000 under our 2021 Plan, subject to continued service as a director through such grant date. Based on an exercise price of \$17.00 per share, which is the initial public offering price of our common stock, each eligible director was granted an option for the purchase of 35,593 shares.

In addition, on the effective date of the registration statement of which this prospectus forms a part, Mr. Wyzga was granted a non-statutory stock option to purchase a number of shares of our common stock with an aggregate Black-Scholes grant-date fair value of \$800,000 under our 2021 Plan, subject to continued service as a director through such grant date. Based on an exercise price of \$17.00 per share, which is the initial public offering price of our common stock, Mr. Wyzga was granted an option for the purchase of 71,186 shares.

### ***Consulting Agreement with Dr. Russo***

In June 2020, we entered into a consulting agreement with Dr. René Russo, a current non-employee member of our board of directors, pursuant to which Dr. Russo is entitled to receive \$7,500 per month, with payment for any partial months prorated. In addition, Dr. Russo's consulting agreement provides that she is eligible for an annual additional consulting fee at the discretion of our board of directors. Such annual additional consulting fee has a target amount of \$40,500, but the actual amount of the annual additional consulting fee is determined by our board of directors in its discretion. This consulting agreement was terminated in connection with this offering.

**EXECUTIVE COMPENSATION**

Our named executive officers for the period from June 3, 2020 (inception) to December 31, 2020, which consisted of our Chief Executive Officer and our two most highly compensated executive officers other than our Chief Executive Officer, were:

- Tillman U. Gerngross, Ph.D., our Co-Founder, Chief Executive Officer and President;
- Lynn Connolly, M.D., Ph.D., our Chief Medical Officer; and
- Rebecca Dabora, Ph.D., our Chief Technology & Manufacturing Officer.

**Summary Compensation Table**

The following table sets forth information regarding compensation awarded to, earned by and paid to our named executive officers with respect to the period from June 3, 2020 (inception) to December 31, 2020.

<u>Name and Principal Position</u>	<u>Salary (\$)</u>	<u>Bonus</u>	<u>Option Awards (\$)(1)</u>	<u>All Other Compensation (\$)</u>	<u>Total (\$)</u>
Tillman U. Gerngross, Ph.D.(2) <i>Co-Founder, Chief Executive Officer and President</i>	—	—	5,941	—	5,941
Lynn Connolly, M.D., Ph.D. <i>Chief Medical Officer</i>	169,154	88,820(4)	584,095	3,767(5)	845,836
Rebecca Dabora, Ph.D. <i>Chief Technology &amp; Manufacturing Officer</i>	357,838(3)	—	225,292	—	583,129

- (1) The amounts reported reflect the aggregate grant-date fair value of option awards granted during the year measured pursuant to Financial Accounting Standard Board Accounting Standards Codification Topic 718, or ASC 718, the basis for computing stock-based compensation in our consolidated financial statements. This calculation assumes that the named executive officer will perform the requisite service for the award to vest in full as required by SEC rules. The assumptions we used in valuing options are described in Note 10 to our audited consolidated financial statements appearing at the end of this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon vesting of the stock options, the exercise of the stock options or the sale of the common stock underlying such stock options.
- (2) Dr. Gerngross is also a member of our board of directors, but he did not receive any additional compensation in his capacity as a director in 2020.
- (3) Represents total hourly compensation paid in 2020 under the terms of the consulting agreement pursuant to which Dr. Dabora provided services to us before her conversion to a full-time employee. See “—Agreements with our Named Executive Officers—Prior Agreements with our Named Executive Officers—Dr. Dabora’s Prior Consulting Agreement.”
- (4) Represents the prorated 2020 annual bonus paid to Dr. Connolly pursuant to the terms of her prior employment agreement with us. See “—Agreements with our Named Executive Officers—Prior Agreements with our Named Executive Officers—Dr. Connolly’s Prior Employment Agreement.”
- (5) Represents employer contributions to Dr. Connolly’s 401(k) plan account and life insurance premiums. See “—Retirement Benefits and Other Compensation.”

## [Table of Contents](#)

### Outstanding Equity Awards at Fiscal 2020 Period-End

The following table sets forth certain information about outstanding equity awards granted to our named executive officers that were outstanding as of December 31, 2020.

Name	Grant Date	Vesting Commence-ment Date	Option Awards (1)				Stock Awards	
			Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable(2)	Option Exercise Price (\$)(3)	Option Expiration Date	Number of shares or units of stock that have not vested (#)	Market Value of shares or units of stock that have not vested (\$)
Tillman U. Gerngross, Ph.D.(4)	—	—	—	—	—	—	1,985,295	9,148,239
Lynn Connolly, M.D., Ph.D.	9/28/2020	7/13/2020	—	860,290(5)	0.78	—	—	—
Rebecca Dabora, Ph.D.	9/28/2020	9/28/2020	—	330,880(5)	0.78	—	—	—

- (1) All of the awards listed in this table were granted under our 2020 Plan. See the section titled “—Equity Incentive Plans—2020 Equity Incentive Plan” below for additional information.
- (2) All of the outstanding stock options were immediately exercisable as of the date of grant, with any unvested shares acquired on exercise subject to a right of repurchase in favor of us at the original exercise price that lapses in accordance with the vesting schedule of the related option. Accordingly, the columns and footnotes below reflect the extent to which stock options held by our named executive officers were vested (as opposed to exercisable) as of December 31, 2020.
- (3) All of the option awards listed in the table were granted with a per share exercise price equal to or above the estimated fair value of our common stock on the date of grant, as determined in good faith by our board of directors.
- (4) Dr. Gerngross’ prior consulting agreement (referred to below) acknowledged that, in consideration of his consulting services, he was granted an option to purchase 1,985,295 shares of our common stock, which option vests as to 25% of the underlying shares on June 15, 2021 and the remainder of the underlying shares vest in 36 substantially equal monthly installments, subject to his continued service through each vesting date. In the event of a “change in control” (as defined our 2020 Plan), the vesting of Dr. Gerngross’s option will accelerate in full, subject to his continued service as of immediately prior to such change in control. The terms of Dr. Gerngross’s option also include the ability for Dr. Gerngross to exercise the option in full on the date of grant. Dr. Gerngross exercised his stock option prior to December 31, 2020 and received unvested shares of our common stock. After exercising his stock option, Dr. Gerngross transferred the unvested shares to Adimab, in exchange for no consideration. Dr. Gerngross is a co-founder and currently serving as Chief Executive Officer and as a director of Adimab. The unvested shares held by Adimab remain subject to the same vesting conditions applicable to Dr. Gerngross’s original option award, including the requirement that Dr. Gerngross continue providing services to us through each vesting date, and such shares are subject to a right of repurchase in favor of us at the original option exercise price that lapses in accordance with such vesting schedule.
- (5) 25% of the shares subject to this award will vest on the first anniversary of the vesting commencement date, with the remaining shares vesting in equal monthly installments over the three years thereafter, in each case subject to the named executive officer’s continued service. Notwithstanding the foregoing, 100% of the shares subject to this award will vest immediately prior to a change in control, subject to the named executive officer’s continued service until immediately prior to such change in control.

## Table of Contents

### **Agreements with our Named Executive Officers**

We have previously entered into employment or consulting agreements with each of our named executive officers, and in connection with this offering, we will enter into employment agreements with Drs. Gerngross and Dabora to supersede their consulting agreement and offer letter, respectively, and a restated and amended employment agreement with Dr. Connolly to supersede her prior employment agreement. The key terms of the prior and prospective agreements are described below. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment or a change in control under the arrangements with our named executive officers, please see “Potential Payments Upon Termination in the Employment Agreements to be Executed in Connection with this Offering” below.

#### ***Prior Agreements with our Named Executive Officers***

##### *Dr. Gerngross’ Prior Consulting Agreement*

In July 2020, we entered into a consulting agreement with Dr. Gerngross. This agreement governs the current terms of Dr. Gerngross’s consulting arrangement with us. Dr. Gerngross’s consulting agreement does not provide for the payment of consulting fees but acknowledges that, in consideration of his consulting services, he was granted an option to purchase 1,985,295 shares of our common stock.

##### *Dr. Connolly’s Prior Employment Agreement*

In November 2020, we entered into an employment agreement with Dr. Connolly. This agreement governs the current terms of Dr. Connolly’s employment with us. Pursuant to her employment agreement, Dr. Connolly is entitled to an annual base salary of \$360,000, and is eligible to receive an annual target bonus equal to 35% of her annual base salary, with the actual payout determined in the discretion our board of directors and any bonus payable in respect of calendar year 2020 prorated from the commencement of her employment. Dr. Connolly is also eligible for standard benefits such as paid time off, for reimbursement of business expenses, and to participate in our employee benefit plans and programs.

##### *Dr. Dabora’s Prior Consulting Agreement*

In June 2020, we entered into a consulting agreement with RDBio Consulting LLC, a limited liability company owned by Dr. Dabora, pursuant to which RDBio Consulting LLC agreed to make Dr. Dabora available to provide services to us. The agreement had an initial term of one year and governed the terms of Dr. Dabora’s service relationship with us before she was converted to a full-time employee. The agreement provided that we pay RDBio Consulting, LLC an amount of \$400 per hour that Dr. Dabora provided services to us (but not to exceed \$3,200 per day). The agreement also provided for reimbursement of business expenses and could be terminated by either party upon 30 days’ prior written notice. In May 2021, Dr. Dabora entered into an offer letter agreement with us, similar in terms to the employment agreement, except that the offer letter did not include severance or change in control benefits.

#### ***Prospective Agreements with our Named Executive Officers***

##### *Dr. Gerngross’s Employment Agreement*

Dr. Gerngross’s employment agreement includes a base salary of \$550,000 and an annual target bonus of 50% of his base salary. The annual bonus will be determined by the compensation committee based on the achievement of performance goals and objectives for the calendar year. The employment agreement provides for standard benefits, such as paid time off, reimbursement of business expenses, and participation in our employee benefit plans and programs. The employment agreement states that any time-based equity issued on or after the offering will not accelerate in full upon a change in control if such equity is assumed, continued or substituted by the successor entity. Severance terms are detailed further below under “Potential Payments Upon Termination in the Employment Agreements to be Executed in Connection with this Offering.”

## Table of Contents

### *Dr. Dabora's Employment Agreement and Dr. Connolly's Restated and Amended Employment Agreement*

Dr. Dabora's employment agreement and Dr. Connolly's restated and amended employment agreement follow the same form as Dr. Gerngross's employment agreement, except that Dr. Dabora will receive a salary of \$400,000 and a target bonus of 40% of her base salary, and Dr. Connolly will receive a salary of \$440,000 and a target bonus of 40% of her base salary. Other substantive differences are limited to the definition of Good Reason, which, for Drs. Dabora and Connolly, is further triggered by a material reduction in the authority, duties or responsibilities of the CEO to whom the executives report. Severance terms are detailed further below under "Potential Payments Upon Termination in the Employment Agreements to be Executed in Connection with this Offering."

### ***Potential Payments Upon Termination in the Employment Agreements to be Executed in Connection with this Offering***

Drs. Gerngross, Connolly and Dabora will be entitled to certain severance and change in control benefits pursuant to the employment agreements executed in connection with this offering.

In the event that the executives' employment ends upon death or a disability, they will be entitled to accrued obligations and payment of their target bonus so long as their employment terminates after the completion of the calendar year but prior to the date of payment of the bonus, or the Earned Bonus.

In the event that employment terminates, other than during the period commencing three months prior to or ending 12 months following a "change in control," or the Change in Control Period, by us without "cause" or by the executive for "good reason" (as defined in our equity plan and the respective employment agreement), and subject to the delivery to us of a separation agreement that includes a general release of claims, Drs. Dabora and Connolly will each receive cash severance equal to nine months of their base salary, as well as the Earned Bonus, if applicable, and nine months continuation of benefits. In exchange for the same terms, Dr. Gerngross will receive cash severance equal to 12 months of his base salary, the Earned Bonus, if applicable, and 12 months continuation of benefits. Each of the three executives will also be entitled to delayed forfeiture of unvested time-based equity awards until 90 days after the date of termination.

In the event that the executives' employment is terminated by us without cause or by the executive for good reason, in either case, during the Change in Control Period, and subject to their delivery to us of a separation agreement that includes a general release of claims, Drs. Dabora and Connolly will each receive cash severance equal to 12 months of their base salary, their respective target bonus for the year of termination, as well as the Earned Bonus, if applicable, and 12 months continuation of benefits. In exchange for the same terms, Dr. Gerngross will receive cash severance equal to 18 months of his base salary, the target bonus for the year of termination with a 1.5 multiplier, the Earned Bonus, if applicable, and 18 months continuation of benefits. All three executives will also be entitled to immediate acceleration and full vesting of any time-based equity awards, exercisable or nonforfeitable as if employment continued until the later of the date of termination or the effective date of the separation agreement.

### **Retirement Benefits and Other Compensation**

Our named executive officers were eligible to participate in our employee benefits, including health insurance and group life insurance benefits, on the same basis as our other employees. We maintain a safe harbor 401(k) plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees are able to defer eligible compensation up to certain limits of the Code, which are updated annually. The 401(k) plan also provides that we will make non-elective contributions each participant's account totaling to 3% of the participant's eligible compensation. We generally do not provide other perquisites or personal benefits except in limited circumstances, and we did not provide any such perquisites or personal benefits to our named executive officers in 2020.

## Equity Incentive Plans

### *2021 Equity Incentive Plan*

Our board of directors adopted, and our stockholders approved, our 2021 Equity Incentive Plan, or the 2021 Plan, in July 2021. Our 2021 Plan provides for the grant of incentive stock options, or ISOs, to employees, including employees of any parent or subsidiary, and for the grant of nonstatutory stock options, or NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards and other forms of stock awards to employees, directors, and consultants, including employees and consultants of our affiliates. Our 2021 Plan is a successor to the 2020 Plan and became effective immediately prior to and contingent upon the execution of the underwriting agreement related to this offering.

*Authorized Shares.* Initially, the maximum number of shares of our common stock that may be issued under our 2021 Plan is 35,075,122 shares, which is the sum of (i) 11,413,572 new shares; plus (ii) the number of shares (not to exceed 23,661,550 shares) equal to (A) the shares that remained available for issuance under the 2020 Plan at the time our 2021 Plan became effective, and (B) 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 our common stock reserved for issuance under our 2021 Plan will automatically increase on January 1 of each calendar year, starting on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 5% of the total number of shares of our 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 our board of directors (in either case, such amount is referred to herein as the annual increase). The maximum number of shares of our common stock that may be issued on the exercise of ISOs under our 2021 Plan shall not exceed the initial reserve cumulatively increased on January 1, 2022 and each January 1st thereafter by the lesser of (i) the annual increase for such year or (ii) 23,827,144 shares of common stock.

Shares subject to stock awards granted under our 2021 Plan that expire or terminate without being exercised in full, or that are paid out in cash rather than in shares, do not reduce the number of shares available for issuance under our 2021 Plan. Additionally, shares become available for future grant under our 2021 Plan if they were issued under stock awards under our 2021 Plan if we repurchase them or they are forfeited. This includes shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award.

*Plan Administration.* Our board of directors, or a duly authorized committee of our board of directors, will administer our 2021 Plan. Our board of directors may also delegate to one or more of our officers the authority to (i) designate employees (other than officers) to receive specified stock awards and (ii) determine the number of shares subject to such stock awards. Under our 2021 Plan, our board of directors has the authority to determine and amend the terms of awards and underlying agreements, including:

- recipients;
- the exercise, purchase or strike price of stock awards, if any; the number of shares subject to each stock award;
- the vesting schedule applicable to the awards, together with any vesting acceleration; and
- the form of consideration, if any, payable on exercise or settlement of the award.

Under the 2021 Plan, the board of directors also generally has the authority to effect, with the consent of any adversely affected participant:

- the reduction of the exercise, purchase, or strike price of any outstanding award;
- the cancellation of any outstanding award and the grant in substitution therefore of other awards, cash, or other consideration; or
- any other action that is treated as a repricing under generally accepted accounting principles.

## Table of Contents

*Stock Options.* ISOs and NSOs are granted under stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for stock options, within the terms and conditions of the 2021 Plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2021 Plan vest at the rate specified in the stock option agreement as determined by the plan administrator.

*Tax Limitations on ISOs.* The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an option holder during any calendar year under all of our stock plans may not exceed \$100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant; and (ii) the option is not exercisable after the expiration of five years from the date of grant.

*Restricted Stock Unit Awards.* Restricted stock units are granted under restricted stock unit award agreements adopted by the plan administrator. Restricted stock units may be granted in consideration for any form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. A restricted stock unit may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan administrator, or in any other form of consideration set forth in the restricted stock unit agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited once the participant's continuous service ends for any reason.

*Restricted Stock Awards.* Restricted stock awards are granted under restricted stock award agreements adopted by the plan administrator. A restricted stock award may be awarded in consideration for cash, check, bank draft or money order, past services to us, or any other form of legal consideration that may be acceptable to our board of directors and permissible under applicable law. The plan administrator determines the terms and conditions of restricted stock awards, including vesting and forfeiture terms. If a participant's service relationship with us ends for any reason, we may receive any or all of the shares of common stock held by the participant that have not vested as of the date the participant terminates service with us through a forfeiture condition or a repurchase right.

*Stock Appreciation Rights.* Stock appreciation rights are granted under stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the purchase price or strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. A stock appreciation right granted under the 2021 Plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

*Performance Awards.* The 2021 Plan permits the grant of performance-based stock and cash awards. The plan administrator may structure awards so that the shares of our stock, cash, or other property will be issued or paid only following the achievement of certain pre-established performance goals during a designated performance period. The performance criteria that will be used to establish such performance goals may be based on any measure of performance selected by the plan administrator. The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (1) to exclude restructuring and/or other nonrecurring charges; (2) to exclude exchange rate effects; (3) to exclude the effects of changes to generally accepted accounting principles; (4) to exclude the effects of any statutory adjustments to corporate tax rates; (5) to exclude the effects of items that are "unusual" in nature or occur "infrequently" as determined under generally accepted accounting principles; (6) to exclude the dilutive



## Table of Contents

effects of acquisitions or joint ventures; (7) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (8) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (9) to exclude the effects of stock based compensation and the award of bonuses under our bonus plans; (10) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under generally accepted accounting principles; (11) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under generally accepted accounting principles; and (12) to exclude the effects of the timing of acceptance for review and/or approval of submissions to the FDA or any other regulatory body. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals. The performance goals may differ from participant to participant and from award to award.

*Other Stock Awards.* The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

*Non-Employee Director Compensation Limit.* The aggregate value of all compensation granted or paid to any non-employee director with respect to any calendar year, including stock awards granted and cash fees paid by us to such non-employee director, will not exceed \$1,500,000 in total value, calculating the value of any such stock awards based on the grant-date fair value of such stock awards for financial reporting purposes.

*Changes to Capital Structure.* In the event there is a specified type of change in our capital structure, such as a stock split, reverse stock split, or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 2021 Plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued on the exercise of incentive stock options, and (iv) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

*Corporate Transactions.* The following applies to stock awards under the 2021 Plan in the event of a corporate transaction, unless otherwise provided in a participant's stock award agreement or other written agreement with us or one of our affiliates or unless otherwise expressly provided by the plan administrator at the time of grant.

In the event of a corporate transaction, any stock awards outstanding under the 2021 Plan may be assumed, continued or substituted for by any surviving or acquiring corporation (or its parent company), and any reacquisition or repurchase rights held by us with respect to the stock award may be assigned to the successor (or its parent company). If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by participants whose continuous service has not terminated prior to the effective time of the transaction, or current participants, the vesting (and exercisability, if applicable) of such stock awards will be accelerated in full to a date prior to the effective time of the transaction (contingent upon the effectiveness of the transaction), and such stock awards will terminate if not exercised (if applicable) at or prior to the effective time of the transaction, and any reacquisition or repurchase rights held by us with respect to such stock awards will lapse (contingent upon the effectiveness of the transaction). With respect to performance awards with multiple vesting levels depending on performance level, unless otherwise provided by an award agreement or by the administrator, the award will accelerate at 100% of target. If the surviving or acquiring corporation (or its parent company) does not assume, continue or substitute for such stock awards, then with respect to any such stock awards that are held by persons other than current participants, such awards will terminate if not exercised (if applicable) prior to the effective time of the transaction, except that any reacquisition or repurchase rights held by us with respect to such stock

## Table of Contents

awards will not terminate and may continue to be exercised notwithstanding the transaction. The plan administrator is not obligated to treat all stock awards or portions of stock awards in the same manner and is not obligated to take the same actions with respect to all participants.

In the event a stock award will terminate if not exercised prior to the effective time of a transaction, the plan administrator may provide, in its sole discretion, that the holder of such stock award may not exercise such stock award but instead will receive a payment equal in value to the excess (if any) of (i) the value of the property the participant would have received upon the exercise of the stock award over (ii) any exercise price payable by such holder in connection with such exercise.

*Change in Control.* In the event of a change in control, as defined under our 2021 Plan, awards granted under our 2021 Plan will not receive automatic acceleration of vesting and exercisability, although this treatment may be provided for in an award agreement.

Under our 2021 Plan, a corporate transaction is defined to include: (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding before such transaction are converted or exchanged into other property by virtue of the transaction, unless otherwise provided in an award agreement or other written agreement between us and the award holder. Under the 2021 Plan, a change in control is defined to include (1) the acquisition by any person or company of more than 50% of the combined voting power of our then outstanding stock; (2) a merger, consolidation or similar transaction in which our stockholders immediately before the transaction do not own, directly or indirectly, more than 50% of the combined voting power of the surviving entity (or the parent of the surviving entity); (3) the approval by the stockholders or the board of directors of a plan of complete dissolution or liquidation of the company, or the occurrence of a complete dissolution or liquidation of the company, except for a liquidation into a parent corporation; (4) a sale, lease, exclusive license or other disposition of all or substantially all of our assets other than to an entity more than 50% of the combined voting power of which is owned by our stockholders; and (5) an unapproved change in the majority of the board of directors.

*Transferability.* A participant may not transfer stock awards under our 2021 Plan other than by will, the laws of descent and distribution, or as otherwise provided under our 2021 Plan.

*Plan Amendment or Termination.* Our board of directors has the authority to amend, suspend, or terminate our 2021 Plan, provided that such action does not materially impair the existing rights of any participant without such participant's written consent. Certain material amendments also require the approval of our stockholders. No incentive stock options may be granted after the tenth anniversary of the date our board of directors adopted our 2021 Plan. No stock awards may be granted under our 2021 Plan while it is suspended or after it is terminated.

### **2020 Equity Incentive Plan**

Our 2020 Equity Incentive Plan, or the 2020 Plan, was originally adopted by our board of directors on June 19, 2020 and approved by our stockholders on June 22, 2020. The 2020 Plan allows for the grant of ISOs to employees, including employees of any parent or subsidiary, and for the grant of NSOs, restricted stock awards, restricted stock units and other forms of stock awards to employees, directors, and consultants. Once our 2021 Plan became effective, no further grants may be made under the 2020 Plan. Any outstanding awards granted under the 2020 Plan will remain subject to the terms of the 2020 Plan and applicable award agreements.

*Authorized Shares.* The maximum number of shares of our common stock that may be issued under the 2020 Plan is 29,254,790 shares. Shares subject to stock awards granted under the 2020 Plan that are cancelled, forfeited, settled in cash or that expire by their terms do not reduce the number of shares available for issuance under the 2020 Plan. Additionally, shares used to pay the exercise price of a stock award or to satisfy the tax withholding obligations related to a stock award become available for future grant under the 2020 Plan.

## Table of Contents

*Administration.* Our board of directors, or a duly authorized committee thereof, administers the 2020 Plan. Under the 2020 Plan, the plan administrator has the full authority and discretion to take any actions it deems necessary or advisable for the 2020 Plan's administration.

*Stock Options.* ISOs and NSOs were granted pursuant to award agreements adopted by the plan administrator. Each award agreement specifies the number of shares subject to the option and the exercise price, provided that the exercise price of a stock option generally cannot be less than 100% (or 110% in the case of ISOs granted to certain stockholders) of the fair market value of our common stock on the date of grant. Options granted under the 2020 Plan vest at the rate specified in the applicable award agreement. Payment for the purchase of common stock issued upon the exercise of a stock option may be made in cash or cash equivalents. However, the plan administrator may also allow for other forms of consideration, including (i) surrendering shares of common stock already owned by a participant, (ii) delivery of a promissory note, (iii) a broker-assisted cashless exercise, (iv) by a "net exercise" arrangement, or (v) by other forms consistent with applicable law. The award agreements specify the term of stock options granted under the 2020 Plan, up to a maximum of 10 years (or five years in the case of ISOs granted to certain stockholders). The plan administrator shall determine the effect on a stock award of the disability, death, retirement, authorized leave of absence, or any other change or purported change in a holder's status. Unless the plan administrator provides otherwise, stock options generally are not transferable except by will, the laws of descent and distribution.

*Changes to Capital Structure.* In the event that the plan administrator determines that any dividend or other distribution, reorganization, merger, consolidation, combination, repurchase, recapitalization, liquidation, dissolution, or sale, transfer, exchange or other disposition of our assets, or sale or exchange of common stock or other securities, issuance of warrants or other rights to purchase common stock or other securities, or other similar corporate transaction or event, affects the common stock such that an adjustment is determined by the administrator to be appropriate, the plan administrator will make appropriate adjustments to the following: (i) the number and kind of shares available for future stock awards, (ii) the number and kind of shares covered by each outstanding stock award, (iii) the grant or exercise price with respect to any award, and (iv) the terms and conditions of any awards (including, without limitation, any applicable financial or other performance "targets" specified in an award agreement).

*Corporate Transactions.* The 2020 Plan provides that in the event of a specified corporate transaction, including without limitation a merger or other consolidation, or the sale or other disposition of all or substantially all of our stock or assets, or in the event of such other corporate transaction, such as a separation or reorganization, the plan administrator will determine how to treat each outstanding stock award. The plan administrator may provide for the:

- settlement of the intrinsic value of stock awards to the extent vested and exercisable awards, with payment made in cash, cash equivalents or property, followed by the cancellation of such stock awards (whether or not then vested or exercisable);
- exercisability and settlement, in whole or in part, of stock awards to the extent vested and exercisable followed by the cancellation of such stock awards (whether or not then vested or exercisable) upon or immediately prior to the effectiveness of the transaction;
- assumption or substitution, in whole or in part, of a stock award by a successor corporation;
- adjustment in the number and type of shares of common stock subject to outstanding awards and/or in the terms and conditions of (including, without limitation, the grant or exercise price), and the criteria included in, outstanding awards;
- replacement of such award with other rights or property selected by the plan administrator; and/or
- termination of such award.

## Table of Contents

*Amendment or Termination.* The plan administrator has the authority to amend, suspend, or terminate the 2020 Plan or any portion thereof at any time, provided that no amendment of the 2020 Plan shall materially and adversely affect (as determined by the plan administrator) any award outstanding at the time of such amendment without the participant's consent. Our board shall obtain stockholder approval of any amendment to the extent necessary to comply with applicable laws.

### **2021 Employee Stock Purchase Plan**

Our board of directors adopted, and our stockholders approved, our 2021 Employee Stock Purchase Plan, or the 2021 ESPP, in July 2021. The 2021 ESPP became effective immediately prior to and contingent upon the execution of the underwriting agreement related to this offering. The purpose of the 2021 ESPP is to secure the services of new employees, to retain the services of existing employees, and to provide incentives for such individuals to exert maximum efforts toward our success and that of our affiliates. The 2021 ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Code for U.S. employees.

*Share Reserve.* Following this offering, the 2021 ESPP authorizes the issuance of shares of our common stock under purchase rights granted to our employees or to employees of any of our designated affiliates. The 2021 ESPP will initially provide participating employees with the opportunity to purchase up to an aggregate of 1,342,773 shares of our common stock. The number of shares of our common stock reserved for issuance will automatically increase on January 1 of each calendar year, starting on January 1, 2022 and continuing through January 1, 2031, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of the automatic increase; and (ii) 2,685,546 shares; provided that before the date of any such increase, our board of directors may determine that such increase will be less than the amount set forth in clauses (i) and (ii). As of the date hereof, no shares of our common stock have been purchased under the 2021 ESPP.

*Administration.* Our board of directors intends to delegate concurrent authority to administer the 2021 ESPP to our compensation committee. The 2021 ESPP is implemented through a series of offerings under which eligible employees are granted purchase rights to purchase shares of our common stock on specified dates during such offerings. Under the 2021 ESPP, we may specify offerings with durations of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering under the 2021 ESPP may be terminated under certain circumstances.

*Payroll Deductions.* Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the 2021 ESPP and may contribute, normally through payroll deductions, up to a certain percentage of their earnings (as defined in the 2021 ESPP) as designated for each offering for the purchase of our common stock under the 2021 ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for the accounts of employees participating in the 2021 ESPP at a price per share that is at least the lesser of (i) 85% of the fair market value of a share of our common stock on the first date of an offering; or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

*Limitations.* Employees may have to satisfy one or more of the following service requirements before participating in the 2021 ESPP, as determined by our board of directors, including (i) being customarily employed for more than 20 hours per week; (ii) being customarily employed for more than five months per calendar year; or (iii) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the 2021 ESPP at a rate in excess of \$25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the 2021 ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value under Section 424(d) of the Code.

## Table of Contents

*Changes to Capital Structure.* In the event there is a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large non-recurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure, or similar transaction, the board of directors will make appropriate adjustments to: (i) the number of shares reserved under the 2021 ESPP; (ii) the maximum number of shares by which the share reserve may increase automatically each year; (iii) the number of shares and purchase price of all outstanding purchase rights; and (iv) the number of shares that are subject to purchase limits under ongoing offerings.

*Corporate Transactions.* In the event of certain significant corporate transactions, including (i) a sale of all or substantially all of our assets; (ii) the sale or disposition of more than 50% of our outstanding securities; (iii) the consummation of a merger or consolidation where we do not survive the transaction; and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately before such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the 2021 ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue, or substitute for such purchase rights, then the participants' accumulated payroll contributions will be used to purchase shares of our common stock within ten business days before such corporate transaction, and such purchase rights will terminate immediately.

*Amendment or Termination.* Our board of directors has the authority to amend or terminate our 2021 ESPP, provided that except in certain circumstances such amendment or termination may not materially impair any outstanding purchase rights without the holder's consent. We will obtain stockholder approval of any amendment to our 2021 ESPP, as required by applicable law or listing requirements.

### **Limitations on Liability and Indemnification Matters**

Upon the closing of this offering, our amended and restated certificate of incorporation will contain provisions that limit the liability of our current and former directors for monetary damages to the fullest extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for any breach of fiduciary duties as directors, except liability for:

- any breach of the director's duty of loyalty to the corporation or its stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases, or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our amended and restated certificate of incorporation and our amended and restated bylaws will provide that we are required to indemnify our directors to the fullest extent permitted by Delaware law. Our amended and restated bylaws will also provide that, upon satisfaction of certain conditions, we are required to advance expenses incurred by a director in advance of the final disposition of any action or proceeding, and permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in that capacity regardless of whether we would otherwise be permitted to indemnify him or her under the provisions of Delaware law. Our amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board.

## [Table of Contents](#)

We have entered into indemnification agreements with each of our directors and expect to enter into indemnification agreements with each of our executive officers prior to the closing of this offering. With certain exceptions, these agreements provide for indemnification for related expenses including, among other things, attorneys' fees, judgments, fines and settlement amounts incurred by any of these individuals in any action or proceeding. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and executive officers. We also maintain customary directors' and officers' liability insurance.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against our directors for breach of their fiduciary duty. They may also reduce the likelihood of derivative litigation against our directors and officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that we pay the costs of settlement and damage awards against directors and officers as required by these indemnification provisions. At present, there is no pending litigation or proceeding involving any of our directors, officers or employees for which indemnification is sought and we are not aware of any threatened litigation that may result in claims for indemnification.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted for our directors, executive officers or persons controlling us, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

### **Rule 10b5-1 Sales Plans**

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from them. The director or officer may amend a Rule 10b5-1 plan in some circumstances and may terminate a plan at any time. Our directors and executive officers also may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information subject to compliance with the terms of our insider trading policy. Prior to 180 days after the date of this offering, subject to early termination, the sale of any shares under such plan would be prohibited by the lock-up agreement that the director or officer has entered into with the underwriters.

## CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of transactions since our inception in June 2020 to which we have been a participant in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or holders of more than 5% of our voting securities, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements that are described under “Management—Non-Employee Director Compensation” and “Executive Compensation.”

### Private Placements of Our Securities

#### *Series A Preferred Stock Financing*

In July 2020, we entered into a preferred stock purchase agreement with certain investors, including beneficial owners of greater than 5% of our capital stock, members of our board of directors and affiliates of members of our board of directors, pursuant to which we issued and sold to such investors an aggregate of 6,237,500 shares of our Series A preferred stock at a purchase price of \$8.00 per share for aggregate gross proceeds of \$49.9 million.

The table below sets forth the aggregate number of shares of Series A preferred stock issued to our related parties in this financing:

<u>Name</u>	<u>Series A Preferred Stock (#)</u>	<u>Aggregate Purchase Price (\$)</u>
Mithril II LP <sup>(1)</sup>	1,250,000	10,000,000
OrbiMed Private Investments VII, LP	812,500	6,500,000
Entities affiliated with Polaris Partners <sup>(2)</sup>	1,250,000	10,000,000
Entities affiliated with GV	687,500	5,500,000
Entities affiliated with FMR, LLC	1,000,000	8,000,000

- (1) Ajay Royan, a member of our board of directors, is the Managing General Partner and Founder of Mithril Capital Management LLC (“MCM”). MCM is a management company that manages Mithril II LP and is appointed by Mithril II GP LP, the general partner of Mithril II LP. Mithril II LP holds more than 5% of our capital stock prior to this offering.
- (2) Terrance McGuire, a member of our board of directors, is a Founding Partner of Polaris Partners. Entities affiliated with Polaris Partners collectively hold more than 5% of our capital stock prior to this offering.

Each share of Series A preferred stock is convertible into five shares of common stock.

#### *Adimab Assignment Agreement*

In July 2020, we issued 5,000,000 shares of our Series A preferred stock in connection with entering into an assignment and license agreement, or the Adimab Assignment Agreement, with Adimab, LLC, or Adimab. At the time of issuance, the 5,000,000 shares of our Series A convertible preferred had a fair value of \$40.0 million. Tillman U. Gerngross, Ph.D., a member of our board of directors and our Chief Executive Officer, is an officer and member of the board of directors of Adimab, Philip Chase, a former member of our board of directors, is an officer and member of the board of directors of Adimab, Laura Walker, Ph.D., our Chief Scientific Officer, is an employee of Adimab, and Terrance McGuire and Ajay Royan, members of our board of directors, are members of the board of directors of Adimab. For more information regarding the Adimab Assignment Agreement, see the section titled “Business—Licensing, Collaborations and Partnerships—Assignment and License Agreement with Adimab.”

## [Table of Contents](#)

### **Series B Preferred Stock Financing**

In October and November 2020, we entered into a preferred stock purchase agreement with certain investors, including beneficial owners of greater than 5% of our capital stock, members of our board of directors and affiliates of members of our board of directors, pursuant to which we issued and sold to such investors an aggregate of 1,410,434 shares of our Series B preferred stock at a purchase price of \$56.72 per share for aggregate gross proceeds of \$80.0 million.

The table below sets forth the aggregate number of shares of Series B preferred stock issued to our related parties in this financing:

<b>Name</b>	<b>Series B Preferred Stock (#)</b>	<b>Aggregate Purchase Price (\$)</b>
Adimab, LLC(1)	44,076	2,499,991
Mithril II LP (2)	176,304	9,999,963
OrbiMed Private Investments VII, LP	88,152	4,999,981
Entities affiliated with Polaris Partners(3)	132,228	7,499,972
Entities affiliated with GV	352,609	19,999,982
Entities affiliated with FMR, LLC	352,609	19,999,982

- (1) (a) Tillman U. Gerngross, Ph.D., a member of our board of directors and our Chief Executive Officer, is an officer and member of the board of directors of Adimab, LLC, (b) Philip Chase, a former member of our board of directors, is an officer and member of the board of directors of Adimab, LLC, (c) Laura Walker, Ph.D., our Chief Scientific Officer, is an employee of Adimab, LLC, and (d) Terrance McGuire and Ajay Royan, members of our board of directors, are members of the board of directors of Adimab, LLC. Adimab, LLC holds more than 5% of our capital stock prior to this offering.
- (2) Ajay Royan, a member of our board of directors, is the Managing General Partner and Founder of Mithril Capital Management LLC (“MCM”). MCM is a management company that manages Mithril II LP and is appointed by Mithril II GP LP, the general partner of Mithril II LP. Mithril II LP holds more than 5% of our capital stock prior to this offering.
- (3) Terrance McGuire, a member of our board of directors, is a Founding Partner of Polaris Partners. Entities affiliated with Polaris Partners collectively hold more than 5% of our capital stock prior to this offering.

Each share of Series B preferred stock is convertible into five shares of common stock.

### **Series C Preferred Stock Financing**

In April 2021, we entered into a preferred stock purchase agreement with certain investors, including beneficial owners of greater than 5% of our capital stock, members of our board of directors and affiliates of members of our board of directors, pursuant to which we issued and sold to such investors an aggregate of 4,296,550 shares of our Series C preferred stock at a purchase price of \$78.08578 per share for aggregate gross proceeds of \$335.5 million.



## Table of Contents

The table below sets forth the aggregate number of shares of Series C preferred stock issued to our related parties in this financing:

Name	Series C Preferred Stock (#)	Aggregate Purchase Price (\$)
Adimab, LLC (1)	128,064	9,999,977
Mithril II LP (2)	422,612	32,999,988
OrbiMed Private Investments VII, LP	96,048	7,499,983
Entities affiliated with RA Capital Management	960,482	74,999,986
Entities affiliated with Polaris Partners (3)	224,112	17,499,960
Entities affiliated with GV	96,048	7,499,983
Entities affiliated with FMR, LLC	640,321	49,999,965

- (1) (a) Tillman U. Gerngross, Ph.D., a member of our board of directors and our Chief Executive Officer, is an officer and member of the board of directors of Adimab, LLC, (b) Philip Chase, a former member of our board of directors, is an officer and member of the board of directors of Adimab, LLC, (c) Laura Walker, Ph.D., our Chief Scientific Officer, is an employee of Adimab, LLC, and (d) Terrance McGuire and Ajay Royan, members of our board of directors, are members of the board of directors of Adimab, LLC. Adimab, LLC holds more than 5% of our capital stock prior to this offering.
- (2) Ajay Royan, a member of our board of directors, is the Managing General Partner and Founder of Mithril Capital Management LLC (“MCM”). MCM is a management company that manages Mithril II LP and is appointed by Mithril II GP LP, the general partner of Mithril II LP. Mithril II LP holds more than 5% of our capital stock prior to this offering.
- (3) Terrance McGuire, a member of our board of directors, is a Founding Partner of Polaris Partners. Entities affiliated with Polaris Partners collectively hold more than 5% of our capital stock prior to this offering.

Each share of Series C preferred stock is convertible into five shares of common stock.

## Agreements with Adimab

### Assignment and License Agreement

We have entered into the Adimab Assignment Agreement pursuant to which Adimab assigned to us all coronavirus antibodies controlled by it, patents claiming such antibodies, know-how related to such antibodies, and biological and chemical materials specifically related to such antibodies, and also granted us a non-exclusive, sublicensable, worldwide, royalty-bearing license to certain of its platform technology to research, develop, make, use and sell coronavirus antibodies and products containing or comprising coronavirus antibodies. In connection with the transfer of the rights acquired and license received, we issued to Adimab 5,000,000 shares of our Series A preferred stock, then having a fair value of \$40.0 million. Concurrently, Adimab relinquished to us 21,250,000 shares of our common stock, then having a fair value of \$85,000. As of July 16, 2021, Adimab held approximately 30.8% of our outstanding capital stock on an as-converted basis.

Under the Adimab Assignment Agreement, we are obligated to pay Adimab quarterly for its services performed under the agreement at a specified full-time equivalent rate. 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. 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 and compulsory licensing.

In February 2021, we achieved the first specified milestone under the agreement upon dosing of the first patient in a Phase 1 clinical trial evaluating ADG20, 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 clinical trial evaluating ADG20 for the prevention of

## **Table of Contents**

COVID-19, which obligated us to make a \$2.5 million payment to Adimab. We made the payment in June 2021. In addition, for the period from June 3, 2020 (inception) to December 31, 2020 and for the three months ended March 31, 2021, we paid Adimab \$0.6 million and \$0.2 million, respectively, in connection with services provided under the Adimab Assignment Agreement. As of December 31, 2020 and March 31, 2021, \$0.6 million and \$0.2 million, respectively, was due to Adimab by us.

For more information on the Adimab Assignment Agreement, see the section titled “Business—Licensing, Collaborations and Partnerships—Assignment and License Agreement with Adimab.”

### ***Collaboration Agreement***

We have also entered into the Adimab Collaboration Agreement, pursuant to which we and Adimab will collaborate on the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. In the event that Adimab discovers an antibody that is expected to meet certain product profiles developed by us, we will have the exclusive option to require Adimab to assign to us its rights in any such antibody and to grant us certain licenses. We entered into the collaboration agreement in May 2021 and are obligated to pay Adimab a quarterly fee of \$1.3 million, 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.

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.

For more information on the Adimab Collaboration Agreement, see the section titled “Business—Licensing, Collaborations and Partnerships—Collaboration Agreement with Adimab.”

Certain of our directors and officers are affiliated with Adimab. Tillman U. Gerngross, Ph.D., a member of our board of directors, our co-founder and Chief Executive Officer and the beneficial owner of 30.8% of our capital stock as of July 16, 2021, is a co-founder and the currently serving Chief Executive Officer of Adimab. Laura Walker, Ph.D., our co-founder and Chief Scientific Officer and a beneficial owner of approximately 1% of our capital stock as of July 16, 2021, is the Senior Director of Antibody Sciences at Adimab. Terrance McGuire, a beneficial owner of 8.9% of our capital stock as of July 16, 2021, and Ajay Royan, a beneficial owner of 10.2% of our capital stock as of July 16, 2021, are each a member of our board of directors and the board of directors of Adimab. Philip Chase, a beneficial owner of 30.8% of our capital stock as of July 16, 2021, is a former member of our board of directors and a member of the board of directors of Adimab.

### **Investors’ Rights, Voting and Right of First Refusal Agreements**

In connection with the sales of preferred stock described above, we entered into an amended and restated investors’ rights agreement, an amended and restated voting agreement and an amended and restated right of first refusal and co-sale agreement containing registration rights, information rights, voting rights and rights of first refusal, among other things, with the holders of our preferred stock. These agreements will terminate upon the

## **Table of Contents**

closing of this offering, except for the registration rights granted under our amended and restated investors' rights agreement, as more fully described in the section of this prospectus titled "Description of Capital Stock—Registration Rights."

### **Consulting Agreements**

We have entered into consulting agreements with certain of our non-employee directors. For more information regarding our consulting agreements with our non-executive directors, see "Management—Non-Employee Director Compensation."

### **Employment Arrangements**

We have entered into employment agreements or offer letter agreements with certain of our executive officers. For more information regarding our employment agreements with our named executive officers, see "Executive Compensation."

### **Indemnification Agreements**

Our amended and restated certificate of incorporation that will be in effect immediately following the closing of this offering will contain provisions limiting the liability of directors, and our amended and restated bylaws will provide that we will indemnify each of our directors to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws will also provide our board of directors with discretion to indemnify our officers and employees when determined appropriate by the board.

In addition, we have entered into indemnification agreements with each of our directors, and we expect to enter into indemnification agreements with each of our executive officers prior to the closing of this offering. For more information regarding these agreements, see "Executive Compensation—Limitations on Liability and Indemnification Matters."

### **Related Person Transaction Policy**

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. In connection with this offering, we have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions, which policy became effective immediately upon the execution of the underwriting agreement for this offering. For purposes of our policy only, a related person transaction will be a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee or director will not be covered by this policy. A related person will be any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our audit committee, or, if audit committee approval would be inappropriate, to another independent body of our board of directors, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from, as the case may be, an unrelated third party or to or from employees generally. Under the policy, we will collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to

## Table of Contents

enable us to identify any existing or potential related-person transactions and to effectuate the terms of the policy. In addition, under our Code of Conduct that we expect to adopt prior to the closing of this offering, our employees and directors will have an affirmative responsibility to disclose any transaction or relationship that reasonably could be expected to give rise to a conflict of interest. In considering related person transactions, our audit committee, or other independent body of our board of directors, will take into account the relevant available facts and circumstances, including:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy will require that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion.

All of the transactions described in this section were entered into prior to the adoption of this policy. Although we have not had a written policy for the review and approval of transactions with related persons, our board of directors has historically reviewed and approved any transaction where a director or officer had a financial interest, including the transactions described above. Prior to approving such a transaction, the material facts as to a director's or officer's relationship or interest in the agreement or transaction were disclosed to our board of directors. Our board of directors took this information into account when evaluating the transaction and in determining whether such transaction was fair to us and in the best interest of all our stockholders.

**PRINCIPAL STOCKHOLDERS**

The following table sets forth information regarding beneficial ownership of our capital stock as of July 16, 2021 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules of the SEC. Under these rules, beneficial ownership includes any shares of common stock as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 90,321,660 shares of common stock outstanding as of July 16, 2021, after giving effect to the conversion of all outstanding shares of our preferred stock. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options held by such person that are currently exercisable or will become exercisable within 60 days of July 16, 2021 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person.

Unless noted otherwise, the address of all listed stockholders is c/o Adagio Therapeutics, Inc., 303 Wyman Street, Suite 300, Waltham, MA 02451.

Except as indicated by the footnotes below, we believe, based on information furnished to us, that each of the stockholders listed has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned	
		Before Offering	After Offering
<b>Greater than 5% stockholders</b>			
Adimab, LLC (1)	27,845,995	30.8%	25.7%
Entities affiliated with FMR, LLC (2)	9,964,650	11.0%	9.2%
Mithril II LP (3)	9,244,580	10.2%	8.5%
Entities affiliated with Polaris Partners (4)	8,031,700	8.9%	7.4%
Entities affiliated with GV (5)	5,680,785	6.3%	5.2%
OrbiMed Private Investments VII, LP (6)	4,983,500	5.5%	4.6%
Entities affiliated with RA Capital Management (7)	4,802,410	5.3%	4.4%
<b>Named Executive Officers and Directors</b>			
Tillman U. Gerngross, Ph.D. (8)	27,845,995	30.8%	25.7%
Lynn Connolly, M.D., Ph.D. (9)	250,915	*	*
Rebecca Dabora, Ph.D.	—	—	—
René Russo, Pharm.D. (10)	1,985,295	2.2%	1.8%
Terrance McGuire (11)	8,031,700	8.9%	7.4%
Ajay Royan (12)	9,244,580	10.2%	8.5%
Howard Mayer, M.D. (13)	58,265	*	*
Anand Shah, M.D.	—	—	—
Tom Heyman	—	—	—
Michael Wyzga	—	—	—
All current executive officers and directors as a group (13 persons)(14)	47,612,630	52.5%	43.7%

\* Represents beneficial ownership of less than one percent.

## Table of Contents

- (1) Consists of (a) 1,985,295 shares of common stock, (b) 25,000,000 shares of common stock issuable upon conversion of Series A preferred stock, (c) 220,380 shares of common stock issuable upon conversion of Series B preferred stock and (d) 640,320 shares of common stock issuable upon conversion of Series C preferred stock. Tillman U. Gerngross, a member of our board of directors and our Chief Executive Officer, is an officer and a member of the board of directors of Adimab, LLC and may be deemed to have shared voting and investment power with respect to the shares held by Adimab, LLC.
- (2) Consists of (a) (i) 2,199,360 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 688,500 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 1,260,760 shares of common stock issuable upon conversion of Series C preferred stock held by Mag & Co fbo Fidelity Growth Company Commingled Pool (FGCCP), (b) (i) 2,069,651 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 747,500 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 1,187,185 shares of common stock issuable upon conversion of Series C preferred stock held by Powhatan & Co., LLC fbo Fidelity Mt. Vernon Street Trust: Fidelity Growth Company Fund (FGCF), (c) (i) 451,810 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 140,680 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 266,440 shares of common stock issuable upon conversion of Series C preferred stock held by Mag & Co fbo Fidelity Mt. Vernon Street Trust: Fidelity Series Growth Company Fund (FSGCF), (d) (i) 279,180 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 90,865 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 487,221 shares of common stock issuable upon conversion of Series C preferred stock held by Powhatan & Co., LLC fbo Fidelity Mt. Vernon Street Trust: Fidelity Growth Company K6 Fund (FGCKF), and (e) 95,500 shares of common stock issuable upon conversion of Series B preferred stock held by Mag & Co fbo Fidelity Select Portfolios: Biotechnology Portfolio (FSPBP, together with FGCCP, FGCF, FSGCF and FGCKF, the Fidelity Funds).

The Fidelity Funds are managed by direct or indirect subsidiaries of FMR LLC. Abigail P. Johnson is a Director, the Chairman, the Chief Executive Officer and the President of FMR LLC.

Members of the Johnson family, including Abigail P. Johnson, are the predominant owners, directly or through trusts, of Series B voting common shares of FMR LLC, representing 49% of the voting power of FMR LLC. The Johnson family group and all other Series B shareholders have entered into a shareholders' voting agreement under which all Series B voting common shares will be voted in accordance with the majority vote of Series B voting common shares. Accordingly, through their ownership of voting common shares and the execution of the shareholders' voting agreement, members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC.

Neither FMR LLC nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act advised by Fidelity Management & Research Company (FMR Co), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds' Boards of Trustees. Fidelity Management & Research Company carries out the voting of the shares under written guidelines established by the Fidelity Funds' Boards of Trustees.

The principal business address for FSGCF, FGCCP and FSPBP referenced in this footnote is c/o Brown Brothers Harriman & Co. Attn: Corporate Actions /Vault 140 Broadway New York, NY 10005.

The principal business address for FGCF and FGCKF referenced in this footnote is c/o BNY Mellon PO Box 392002, Pittsburgh PA 15230.

- (3) Consists of (a) 6,250,000 shares of common stock issuable upon conversion of Series A preferred stock, (b) 881,520 shares of common stock issuable upon conversion of Series B preferred stock and (c) 2,113,060 shares of common stock issuable upon conversion of Series C preferred stock. The percentage of shares beneficially owned after this offering does not include 1,997,000 shares of common stock that we directed the underwriters to allocate to Mithril II LP at the initial public offering price and on the same terms as the other shares of common stock being offered in this offering. Ajay Royan, a member of our board of directors, is the Managing General Partner and Founder of Mithril Capital Management LLC, ("MCM"). MCM is a management company that manages Mithril II LP and is appointed by Mithril II GP LP ("GP II"), the general

## Table of Contents

partner of Mithril II LP. Peter Thiel and Ajay Royan are the members of the investment committee GP II. The investment committee makes all investment decisions with respect to these entities and may be deemed to share voting and investment power over the securities held by Mithril II LP.

- (4) Consists of (a) (i) 1,809,250 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 425,305 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 617,870 shares of common stock issuable upon conversion of Series C preferred stock held by Polaris Venture Partners V, L.P. (PVP V), (b) (i) 35,260 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 8,290 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 12,045 shares of common stock issuable upon conversion of Series C preferred stock held by Polaris Venture Partners Entrepreneurs' Fund V, L.P. (PVPEF V), (c) (i) 12,395 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 2,915 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 4,230 shares of common stock issuable upon conversion of Series C preferred stock held by Polaris Venture Partners Founders' Fund V, L.P. (PVPFF V), (d) (i) 18,095 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 4,250 shares of common stock issuable upon conversion of Series B convertible preferred stock and (iii) 6,175 shares of common stock issuable upon conversion of Series C preferred stock held by Polaris Venture Partners Special Founders' Fund V, L.P. (PVPSFF V, together with PVP V, PVPEF V, and PVPFF V, the Polaris V Funds), (e) (i) 4,375,000 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 220,380 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 160,080 shares of common stock issuable upon conversion of Series C preferred stock held by Polaris Partners IX, L.P. (PP IX), and (f) 320,160 shares of common stock issuable upon conversion of Series C preferred stock held by Polaris Healthcare Technology Opportunities Fund, L.P. (PHCT).

Polaris Venture Management Co. V, L.L.C. (PVM V) is the general partner of each of the Polaris V Funds and may be deemed to have shared voting and investment power with respect to the shares held by each of the Polaris V Funds. Jonathan A. Flint and Mr. McGuire (collectively, the PVM V Managing Members) are the managing members of PVM V and may be deemed to have shared voting and investment power with respect to the shares held by each of the Polaris V Funds.

Polaris Partners GP IX, L.L.C. (PP GP IX) is the general partner of PP IX and may be deemed to have shared voting and investment power with respect to the shares held by PP IX. David Barrett, Brian Chee, Amir Nashat and Amy Schulman (collectively, the PP GP IX Managing Members) are the managing members of PP GP IX and Mr. McGuire holds an interest in PP GP IX. Each of the PP GP IX Managing Members and Mr. McGuire, in their respective capacities with respect to PP GP IX, may be deemed to have shared voting and investment power with respect to the shares held by PP IX.

Polaris Healthcare Technology Opportunities Fund GP, L.L.C. (PHCT GP) is the general partner of PHCT and may be deemed to have shared voting and investment power with respect to the shares held by PHCT. David Barrett, Brian Chee, Amir Nashat and Amy Schulman (collectively, the PHCT GP Managing Members) are the managing members of PHCT GP and Mr. McGuire holds an interest in PHCT GP. Each of the PHCT GP Managing Members and Mr. McGuire, in their respective capacities with respect to PHCT GP, may be deemed to have shared voting and investment power with respect to the shares held by PHCT.

The principal business address for all entities and individuals referenced in this footnote is c/o Polaris Partners, One Marina Park Drive, 10th Floor, Boston, Massachusetts 02210.

- (5) Consists of (a) 3,437,500 shares of common stock issuable upon conversion of Series A preferred stock held by GV 2019, L.P. (GV 2019), (b) 1,763,045 shares of common stock issuable upon conversion of Series B preferred stock held by GV 2019, and (c) 480,240 shares of common stock issuable upon conversion of Series C preferred stock held by GV 2021, L.P. (GV 2021).

GV 2019 GP, L.P., the general partner of GV 2019, GV 2019 GP, L.L.C., the general partner of GV 2019 GP, L.P., Alphabet Holdings LLC, the managing member of GV 2019 GP, L.L.C., XXVI Holdings Inc., the managing member of Alphabet Holdings LLC, and Alphabet Inc., the controlling stockholder of XXVI Holdings Inc., may each be deemed to have shared voting and investment power with respect to the shares held GV 2019.



## Table of Contents

GV 2021 GP, L.P., the general partner of GV 2021, GV 2021 GP, L.L.C., the general partner of GV 2021 GP, L.P., Alphabet Holdings LLC, the managing member of GV 2021 GP, L.L.C., XXVI Holdings Inc., the managing member of Alphabet Holdings LLC, and Alphabet Inc., the controlling stockholder of XXVI Holdings Inc., may each be deemed to have shared voting and investment power with respect to the shares held GV 2021.

Each of the entities described above as being affiliated with GV 2019, L.P. and/or GV 2021, L.P. is subject to the ultimate control of Alphabet Inc., a publicly traded company.

The principal business address for all entities referenced in this footnote is 1600 Amphitheatre Parkway, Mountain View, CA 94043.

- (6) Consists of (a) 4,062,500 shares of common stock issuable upon conversion of Series A preferred stock, (b) 440,760 shares of common stock issuable upon conversion of Series B preferred stock and (c) 480,240 shares of common stock issuable upon conversion of Series C preferred stock. OrbiMed Capital GP VII LLC (OrbiMed GP VII) is the general partner of OrbiMed Private Investments VII, LP (OPI VII). OrbiMed Advisors LLC (OrbiMed Advisors) is the managing member of OrbiMed GP VII. OrbiMed GP VII and OrbiMed Advisors may be deemed to have shared voting and investment power with respect to the shares held by OPI VII. OrbiMed Advisors exercises investment and voting power through a management committee comprised of Carl L. Gordon, Sven H. Borho and Jonathan T. Silverstein, each of whom disclaims beneficial ownership of the shares held by OPI VII.
- (7) Consists of (a) 4,082,050 shares of common stock issuable upon conversion of Series C preferred stock held by RA Capital Healthcare Fund, L.P. (RA Healthcare), and (b) 720,360 shares of common stock issuable upon conversion of Series C preferred stock held by RA Capital Nexus Fund II, L.P. (Nexus II). RA Capital Management, L.P., is the investment manager for RA Healthcare and Nexus II. The general partner of RA Capital Management, L.P., is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the managing members. RA Capital Management, L.P., RA Capital Management GP, LLC, Peter Kolchinsky and Rajeev Shah may be deemed to have shared voting and investment power with respect to the shares held RA Healthcare and Nexus II. The address of all entities and individuals referenced in this footnote is 200 Berkeley Street, 18th Floor, Boston, Massachusetts 02116.
- (8) Consists of (a) 1,985,295 shares of common stock, (b) 25,000,000 shares of common stock issuable upon conversion of Series A preferred stock, (c) 220,380 shares of common stock issuable upon conversion of Series B preferred stock and (d) 640,320 shares of common stock issuable upon conversion of Series C preferred stock held by Adimab, LLC. Dr. Gerngross is an officer and member of the board of directors of Adimab, LLC and may be deemed to have shared voting and investment power with respect to the shares held by Adimab, LLC.
- (9) Consists of 250,915 shares of common stock issuable upon the exercise of options within 60 days of July 16, 2021.
- (10) Consists of 1,985,295 shares of common stock. Shares are subject to a right of repurchase in favor of us at the original option exercise price that lapses in accordance with such vesting schedule.
- (11) Consists of (a) (i) 1,809,250 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 425,305 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 617,870 shares of common stock issuable upon conversion of Series C preferred stock held by PVP V, (b) (i) 35,260 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 8,290 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 12,045 shares of common stock issuable upon conversion of Series C preferred stock held by PVPEF V, (c) (i) 12,395 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 2,915 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 4,230 shares of common stock issuable upon conversion of Series C preferred stock held by PVPF V, (d) (i) 18,095 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 4,250 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 6,175 shares of common stock issuable upon conversion of Series C preferred stock held by PVPSFF V, (e) (i) 4,375,000 shares of common stock issuable upon conversion of Series A preferred stock, (ii) 220,380 shares of common stock issuable upon conversion of Series B preferred stock and (iii) 160,080 shares of common stock issuable upon conversion of Series C preferred stock held by PP



## Table of Contents

IX, and (f) 320,160 shares of common stock issuable upon conversion of Series C preferred stock held by PHCT. Mr. McGuire is a Founding Partner of Polaris Partners and may be deemed to have shared voting and investment power with respect to the shares held by all entities affiliated with Polaris Partners.

- (12) Consists of (a) 6,250,000 shares of common stock issuable upon conversion of Series A preferred stock, (b) 881,520 shares of common stock issuable upon conversion of Series B preferred stock and (c) 2,113,060 shares of common stock issuable upon conversion of Series C preferred stock held by Mithril II LP. Mr. Royan is the Managing General Partner and Founder of Mithril Capital Management LLC ("MCM"). MCM is a management company that manages Mithril II LP and is appointed by Mithril II GP LP ("GP II"), the general partner of Mithril II LP. Peter Thiel and Ajay Royan are the members of the investment committee GP II. The investment committee makes all investment decisions with respect to these entities and may be deemed to share voting and investment power over the securities held by Mithril II LP.
- (13) Consists of 58,265 shares of common stock issuable upon the exercise of options within 60 days of July 16, 2021.
- (14) Consists of (a) 47,107,570 shares of common stock beneficially owned by named executive officers and directors, (b) 127,060 shares of common stock beneficially owned by other executive officers and (c) 378,000 shares of common stock issuable upon the exercise of options within 60 days of July 16, 2021.

## DESCRIPTION OF CAPITAL STOCK

*The following description of our capital stock, certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws, as each will be in effect following the completion of this offering, and certain provisions of Delaware law are summaries. You should also refer to the amended and restated certificate of incorporation and the amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is part.*

### General

Immediately following the completion of this offering, our amended and restated certificate of incorporation will authorize us 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 will be undesignated. Our board of directors may establish the rights and preferences of the preferred stock from time to time.

As of March 31, 2021, we had outstanding 5,593,240 shares of common stock, held by six stockholders of record. As of March 31, 2021, after giving effect to the conversion of all outstanding shares of our preferred stock, there would have been 68,832,910 shares of common stock outstanding, held by 32 stockholders of record.

### Common Stock

#### *Voting Rights*

Each holder of our 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<sup>2</sup>/<sub>3</sub>% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our 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 our 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 our 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 we may designate in the future.

## [Table of Contents](#)

### **Preferred Stock**

As of March 31, 2021, there were 12,647,934 shares of our preferred stock outstanding, consisting of 11,237,500 shares of our Series A preferred stock, 1,410,434 shares of our Series B preferred stock and no shares of our Series C preferred stock. We issued 4,296,550 shares of our Series C preferred stock in April 2021. All currently outstanding shares of preferred stock will be converted into an aggregate of 84,722,420 shares of common stock upon the closing of this offering.

Following the closing of this offering, our board of directors will have the authority under our amended and restated certificate of incorporation, without further action by our stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock. The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in control of us and may adversely affect the market price of our common stock and the voting and other rights of the holders of our common stock. It is not possible to state the actual effect of the issuance of any shares of preferred stock on the rights of holders of common stock until the board of directors determines the specific rights attached to that preferred stock. Following the completion of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

### **Options**

As of March 31, 2021, there were options to purchase 5,366,070 shares of common stock outstanding. For additional information regarding the terms of our 2020 Equity Incentive Plan, see “Executive Compensation—Equity Incentive Plans.”

### **Registration Rights**

We, the holders of our existing preferred stock and certain holders of our existing common stock have entered into an amended and restated investors’ rights agreement. The registration rights provisions of this agreement provide those holders with demand, piggyback and Form S-3 registration rights with respect to the shares of common stock currently held by them and issuable to them upon conversion of our preferred stock in connection with our initial public offering. These shares are collectively referred to herein as registrable securities.

#### ***Demand Registration Rights***

At any time beginning 180 days following the effective date of the registration statement of which this prospectus is a part, the holders of a majority of registrable securities then outstanding have the right to demand that we file a registration statement covering at least 30% of the registrable securities then outstanding. These registration rights are subject to specified conditions and limitations, including the right of the underwriters, if any, to limit the number of shares included in any such registration under specified circumstances. Upon such a request, we are required to effect the registration as soon as practicable, but in any event no later than 60 days after the receipt of such request. An aggregate of 84,722,420 shares of common stock will be entitled to these demand registration rights.

### ***Piggyback Registration Rights***

If we propose to register any of our securities under the Securities Act either for our own account or for the account of other stockholders, the holders of registrable securities will each be entitled to notice of the registration and will be entitled to include their shares of common stock in the registration statement. These piggyback registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under specified circumstances. An aggregate of 84,722,420 shares of common stock will be entitled to these piggyback registration rights.

### ***Registration on Form S-3***

At any time after we become eligible to file a registration statement on Form S-3, the holders of at least 30% of the registrable securities then outstanding will be entitled to request to have such shares registered by us on a Form S-3 registration statement. These Form S-3 registration rights are subject to other specified conditions and limitations, including the condition that the anticipated aggregate offering price is at least \$1.0 million. Upon receipt of this request, the holders of registrable securities will each be entitled to participate in this registration. An aggregate of 84,722,420 shares of common stock will be entitled to these Form S-3 registration rights.

### ***Expenses of Registration***

We are required to pay all expenses, including fees and expenses of one counsel to represent the selling stockholders, relating to any demand, piggyback or Form S-3 registration, other than underwriting discounts and commissions, stock transfer taxes and any additional fees of counsel for the selling stockholders, subject to specified conditions and limitations. We are not required to pay registration expenses if a demand registration request is withdrawn at the request of a majority of holders of registrable securities to be registered, unless holders of a majority of the registrable securities agree to forfeit their right to one demand registration.

The second amended and restated investors' rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the applicable registration statement attributable to us, and the selling stockholders are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them, subject to certain limitations.

### ***Termination of Registration Rights***

The registration rights granted under the investors' rights agreement will terminate with respect to any particular stockholder upon the earlier of (a) the closing of a deemed liquidation event, as defined in our certificate of incorporation, (b) with respect to each stockholder, at such time such stockholder is able to sell all of its shares pursuant to Rule 144 or another similar exemption under the Securities Act during a three-month period without registration and (c) the fifth anniversary of the closing of this offering.

## **Anti-Takeover Provisions**

### ***Section 203 of the Delaware General Corporation Law***

We are 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

## Table of Contents

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<sup>2</sup>/<sub>3</sub>% 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, transfer, pledge or other disposition of 10% or more of the assets of the corporation 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 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.

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***

Our amended and restated certificate of incorporation to be in effect upon the completion of this offering, or our restated certificate, will provide for our 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 our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our restated certificate and our amended and restated bylaws to be effective upon the completion of this offering, or our restated bylaws, will also provide that directors may be removed by the stockholders only for cause upon the vote of 66<sup>2</sup>/<sub>3</sub>% or more of our outstanding common 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, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

Under our restated certificate of incorporation and amended and restated bylaws our stockholders will not have cumulative voting rights. Because of this, the holders of a majority of the shares of common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they should so choose.

Our restated certificate and restated bylaws will also provide that all stockholder actions must be effected at a duly called meeting of stockholders and will eliminate the right of stockholders to act by written consent without a meeting. Our restated bylaws will also provide that only our Chairman of the board, 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.

## Table of Contents

Our restated bylaws will 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 will specify requirements as to the form and content of a stockholder's notice.

Our restated certificate and restated bylaws will provide that the stockholders cannot amend many of the provisions described above except by a vote of 66<sup>2</sup>/<sub>3</sub>% or more of our outstanding common stock.

As described in "—Preferred Stock" above, our restated certificate will give our board of directors the authority, without further action by our 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 will make it more difficult for our existing stockholders to replace our board of directors as well as for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our 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 our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce our 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 our shares and may have the effect of delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts. We believe that the benefits of these provisions, including increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure our company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

### **Choice of Forum**

Our amended and restated certificate of incorporation will provide that the Court of Chancery of the state of Delaware will be 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 pursuant to the Delaware General Corporation Law, our restated certificate, or our amended and restated bylaws; or
- any action asserting a claim against us that is governed by the internal affairs doctrine.

The 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 will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

---

## **Table of Contents**

While the Delaware courts have determined that such choice of forum provisions are facially valid, 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 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

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.

Our amended and restated certificate of incorporation will further provide 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, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

### **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. The transfer agent's address is 6201 15th Avenue, Brooklyn, New York 11219.

### **Listing**

Our common stock has been approved for listing on the Nasdaq Global Market under the trading symbol "ADGI."

## SHARES ELIGIBLE FOR FUTURE SALE

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

Upon the closing of this offering, we will have outstanding 108,515,660 shares of our common stock, based on the 5,593,240 shares of our common stock that were outstanding on March 31, 2021, after giving effect to the issuance of 18,200,000 shares of our common stock in this offering, assuming no exercise by the underwriters of their option to purchase additional shares of our common stock and the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 84,722,420 shares of common stock upon the closing of this offering. All of the shares of common stock sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any shares sold to our “affiliates,” as that term is defined under Rule 144 under the Securities Act. The remaining 90,315,660 shares of common stock held by existing stockholders are “restricted securities,” as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if registered or if their resale qualifies for exemption from registration described below under Rule 144 promulgated under the Securities Act or another available exemption.

As a result of the lock-up agreements described below and the provisions of Rules 144 and 701 under the Securities Act, the shares of common stock that will be deemed restricted securities after this offering will be available for sale in the public market as follows:

- none of the existing restricted shares will be eligible for immediate sale upon the completion of this offering; and
- 90,321,660 restricted shares (which includes 6,000 restricted shares issued subsequent to March 31, 2021) will be eligible for sale in the public market upon expiration of lock-up agreements 180 days after the date of this prospectus, subject in certain circumstances to the volume, manner of sale and other limitations under Rule 144 and Rule 701 under the Securities Act, which are summarized below.

### Rule 144

In general, non-affiliate persons who have beneficially owned restricted shares of our common stock for at least six months, and any affiliate of the company who owns either restricted or unrestricted shares of our common stock, are entitled to sell their securities without registration with the SEC under an exemption from registration provided by Rule 144 under the Securities Act.

#### *Non-Affiliates*

Any person who is not deemed to have been one of our affiliates at the time of, or at any time during the three months preceding, a sale may sell an unlimited number of restricted securities under Rule 144 if:

- the restricted securities have been held for at least six months, including the holding period of any prior owner other than one of our affiliates (subject to certain exceptions);
- we have been subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale; and
- we are current in our Exchange Act reporting at the time of sale.

Any person who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale and has held the restricted securities for at least one year, including the holding period of any prior owner other than one of our affiliates, will be entitled to sell an unlimited number of restricted



## [Table of Contents](#)

securities without regard to the length of time we have been subject to Exchange Act periodic reporting or whether we are current in our Exchange Act reporting. Non-affiliate resales are not subject to the manner of sale, volume limitation or notice filing provisions of Rule 144.

### ***Affiliates***

Persons seeking to sell restricted securities who are our affiliates at the time of, or any time during the three months preceding, a sale, would be subject to the restrictions described above. They are also subject to additional restrictions, by which such person would be required to comply with the manner of sale and notice provisions of Rule 144 and would be entitled to sell within any three-month period only that number of securities that does not exceed the greater of either of the following:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 1,085,156 shares immediately after the completion of this offering based on the number of shares outstanding as of March 31, 2021; or
- the average weekly trading volume of our common stock on the stock exchange on which our shares are listed during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Additionally, persons who are our affiliates at the time of, or any time during the three months preceding, a sale may sell unrestricted securities under the requirements of Rule 144 described above, without regard to the six-month holding period of Rule 144, which does not apply to sales of unrestricted securities.

### **Rule 701**

Rule 701 under the Securities Act, as in effect on the date of this prospectus, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers or directors who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the date of this prospectus before selling their shares. However, substantially all Rule 701 shares are subject to lock-up agreements as described below and in the section titled “Underwriting” and will become eligible for sale upon the expiration of the restrictions set forth in those agreements.

### **Form S-8 Registration Statements**

We intend to file one or more registration statements on Form S-8 under the Securities Act to register all shares of common stock subject to outstanding stock options and common stock issued or issuable under our equity plans. We expect to file the registration statement covering shares offered pursuant to our stock plans as soon as practicable after the closing of this offering, permitting the resale of such shares by non-affiliates in the public market without restriction under the Securities Act and the sale by affiliates in the public market, subject to compliance with the resale provisions of Rule 144 and expiration or release from the terms of the lock-up agreements described above.

### **Lock-Up Agreements**

We, our executive officers and directors and approximately 100% of the holders of our common stock outstanding on the date of this prospectus have entered into lock-up agreements with the underwriters or otherwise agreed, subject to certain exceptions, that we and they will not, directly or indirectly, offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale, or otherwise dispose of or hedge any of our shares of common stock, any options or warrants to purchase shares of our common stock, or any securities convertible into, or exchangeable for or that represent the right to receive shares of our common stock, without the prior written consent of Morgan Stanley & Co. LLC and Jefferies LLC for a period of 180 days from the date of this prospectus.

---

## [Table of Contents](#)

In addition to the restrictions contained in the lock-up agreements described above, we have entered into an agreement with the holders of our preferred stock that contains market stand-off provisions imposing restrictions on the ability of such security holders to sell or otherwise transfer or dispose of any registrable securities for a period of 180 days following the date of this prospectus.

### **Registration Rights**

Upon the closing of this offering, the holders of 84,722,420 shares of our common stock, including common stock issuable upon the conversion of our preferred stock, or their transferees, will be entitled to specified rights with respect to the registration of their registrable shares under the Securities Act, subject to certain limitations and the expiration, waiver or termination of the lock-up agreements. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act immediately upon effectiveness of the registration. See “Description of Capital Stock—Registration Rights” for additional information.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following is a summary of certain material U.S. federal income tax consequences to non-U.S. holders (as defined below) of the ownership and disposition of our common stock offered pursuant to this prospectus. This discussion is not a complete analysis of all potential U.S. federal income tax consequences relating thereto, does not address the potential application of the Medicare contribution tax on net investment income, the alternative minimum tax, or the special tax accounting rules under Section 451(b) of the Code, and does not address any U.S. federal non-income tax consequences such as estate or gift tax consequences or any tax consequences arising under any state, local, or non-U.S. tax laws, or any other U.S. federal tax laws. This discussion is based on the Code and applicable Treasury Regulations promulgated thereunder, judicial decisions and published rulings, and administrative pronouncements of the Internal Revenue Service, or IRS, all as in effect as of the date hereof. These authorities are subject to differing interpretations and may change, possibly retroactively, resulting in U.S. federal income tax consequences different from those discussed below. We have not requested a ruling from the IRS with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS or a court will agree with such statements and conclusions.

This discussion is limited to non-U.S. holders who purchase our common stock offered by this prospectus and who hold our common stock as a “capital asset” within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all of the U.S. federal income tax consequences that may be relevant to a particular holder in light of such holder’s particular circumstances. This discussion also does not consider any specific facts or circumstances that may be relevant to holders subject to special rules under the U.S. federal income tax laws, including:

- certain former citizens or long-term residents of the United States;
- partnerships or other entities or arrangements treated as partnerships, pass-throughs, or disregarded entities for U.S. federal income tax purposes (and investors therein), S corporations or other pass-through entities (including hybrid entities);
- “controlled foreign corporations;”
- “passive foreign investment companies;”
- corporations that accumulate earnings to avoid U.S. federal income tax;
- banks, financial institutions, investment funds, insurance companies, brokers or dealers in securities;
- persons who have elected to mark securities to market;
- tax-exempt organizations and governmental organizations;
- tax-qualified retirement plans;
- persons that acquired our common stock through the exercise of employee stock options or otherwise as compensation or through a tax-qualified retirement plan;
- persons that acquired our common stock pursuant to the exercise of warrants or conversion rights under convertible instruments;
- persons who hold common stock that constitutes “qualified small business stock” under Section 1202 of the Code, or “Section 1244 stock” under Section 1244 of the Code;
- persons who acquired our common stock in a transaction subject to the gain rollover provisions of the Code (including Section 1045 of the Code);
- persons that own, or have owned, actually or constructively, more than 5% of our common stock;

## Table of Contents

- “qualified foreign pension funds” as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons holding our common stock as part of a hedging or conversion transaction or straddle, or a constructive sale, or other risk reduction strategy or integrated investment.

If an entity or arrangement that is classified as a partnership for U.S. federal income tax purposes holds our common stock, the U.S. federal income tax treatment of a partner in the partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships holding our common stock and the partners in such partnerships are urged to consult their tax advisors about the particular U.S. federal income tax consequences to them of holding and disposing of our common stock.

**THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. PROSPECTIVE INVESTORS SHOULD CONSULT THEIR TAX ADVISORS REGARDING THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES TO THEM OF ACQUIRING, OWNING, AND DISPOSING OF OUR COMMON STOCK, AS WELL AS ANY TAX CONSEQUENCES ARISING UNDER ANY STATE, LOCAL, OR NON-U.S. TAX LAWS AND ANY U.S. FEDERAL NON-INCOME TAX LAWS, OR UNDER ANY APPLICABLE INCOME TAX TREATY.**

### **Definition of Non-U.S. Holder**

For purposes of this discussion, a non-U.S. holder is any beneficial owner of our common stock that is not a “U.S. person” or a partnership (including any entity or arrangement treated as a partnership) for U.S. federal income tax purposes. A U.S. person is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust (1) whose administration is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (2) that has a valid election in effect under applicable Treasury Regulations to be treated as a U.S. person.

### **Distributions on Our Common Stock**

As described in the section titled “Dividend Policy,” we have not paid and do not anticipate paying dividends in the foreseeable future. However, if we make cash or other property distributions on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts that exceed such current and accumulated earnings and profits and, therefore, are not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and will first be applied against and reduce a holder’s tax basis in our common stock, but not below zero. Any amount distributed in excess of basis will be treated as gain realized on the sale or other disposition of our common stock and will be treated as described under the section titled “—Gain on Disposition of Our Common Stock” below.

Subject to the discussions below regarding effectively connected income, backup withholding, and Sections 1471 through 1474 of the Code, or FATCA, dividends paid to a non-U.S. holder of our common stock generally will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends or such lower rate specified by an applicable income tax treaty. To receive the benefit of a reduced treaty rate, a non-U.S. holder must furnish us or the applicable withholding agent with a valid IRS Form W-8BEN or IRS Form W-8BEN-E (or applicable successor form) certifying such holder’s qualification for the reduced rate. This

## Table of Contents

certification must be provided to us or the applicable withholding agent before the payment of dividends and must be updated periodically. If the non-U.S. holder holds the stock through a financial institution or other agent acting on the non-U.S. holder's behalf, the non-U.S. holder will be required to provide appropriate documentation to the agent, which then will be required to provide certification to us or the applicable withholding agent, either directly or through other intermediaries.

Non-U.S. holders that do not provide the required certification on a timely basis, but that qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS.

If a non-U.S. holder holds our common stock in connection with the conduct of a trade or business in the United States, and dividends paid on our common stock are effectively connected with such holder's U.S. trade or business (and are attributable to such holder's permanent establishment in the United States, if required by an applicable tax treaty), the non-U.S. holder will generally be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must generally furnish a valid IRS Form W-8ECI (or applicable successor form) to the applicable withholding agent.

However, any such effectively connected dividends paid on our common stock generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

### **Gain on Disposition of Our Common Stock**

Subject to the discussions below regarding backup withholding and FATCA, a non-U.S. holder generally will not be subject to U.S. federal income tax on any gain realized on the sale or other disposition of our common stock, unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if required by an applicable income tax treaty, is attributable to a permanent establishment maintained by the non-U.S. holder in the United States;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition, and certain other requirements are met; or
- our common stock constitutes a "United States real property interest" by reason of our status as a United States real property holding corporation, or USRPHC, for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition or the non-U.S. holder's holding period for our common stock, and our common stock is not regularly traded on an established securities market as defined by applicable Treasury Regulations.

Determining whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our foreign real property interests. We do not believe that we are, or have been, and do not anticipate becoming, a USRPHC for U.S. federal income tax purposes, although there can be no assurance we will not in the future become a USRPHC. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition by a non-U.S. holder of our common stock may not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular U.S. federal income tax rates in the same manner as if such holder were a resident of

## **Table of Contents**

the United States. A non-U.S. holder that is a foreign corporation also may be subject to an additional branch profits tax equal to 30% (or such lower rate specified by an applicable income tax treaty) of its effectively connected earnings and profits for the taxable year, as adjusted for certain items. Gain described in the second bullet point above will be subject to U.S. federal income tax at a flat 30% rate (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S.-source capital losses (even though the individual is not considered a resident of the United States), provided that the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses. Non-U.S. holders should consult their tax advisors regarding any applicable income tax treaties that may provide for different rules.

### **Information Reporting and Backup Withholding**

Annual reports are required to be filed with the IRS and provided to each non-U.S. holder indicating the amount of distributions on our common stock paid to such holder and the amount of any tax withheld with respect to those distributions. These information reporting requirements apply even if no withholding was required (because the distributions were effectively connected with the holder's conduct of a U.S. trade or business, or withholding was reduced or eliminated by an applicable income tax treaty) and regardless of whether such distributions constitute dividends. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. Backup withholding, currently at a 24% rate, generally will not apply to payments to a non-U.S. holder of dividends on or the gross proceeds of a disposition of our common stock provided the non-U.S. holder furnishes the required certification for its non-U.S. status, such as by providing a valid IRS Form W-8BEN, IRS Form W-8BEN-E, or IRS Form W-8ECI, or certain other requirements are met. Backup withholding may apply if the payor has actual knowledge, or reason to know, that the holder is a U.S. person who is not an exempt recipient.

Backup withholding is not an additional tax. If any amount is withheld under the backup withholding rules, the non-U.S. holder should consult with a U.S. tax advisor regarding the possibility of and procedure for obtaining a refund or a credit against the non-U.S. holder's U.S. federal income tax liability, if any.

### **Withholding on Foreign Entities**

FATCA imposes a U.S. federal withholding tax of 30% on certain payments made to a "foreign financial institution" (as specially defined under these rules) unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding certain U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners) or an exemption applies. FATCA also generally will impose a U.S. federal withholding tax of 30% on certain payments made to a non-financial foreign entity unless such entity provides the withholding agent a certification identifying certain direct and indirect U.S. owners of the entity or an exemption applies. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Under certain circumstances, a non-U.S. holder might be eligible for refunds or credits of such taxes. FATCA applies to dividends paid on our common stock and, subject to the proposed Treasury Regulations described below, also applies to gross proceeds from sales or other dispositions of our common stock. The U.S. Treasury Department released proposed Treasury Regulations which, if finalized in their present form, would eliminate the federal withholding tax of 30% applicable to the gross proceeds of a disposition of our common stock. In its preamble to such proposed Treasury Regulations, the U.S. Treasury Department stated that taxpayers may generally rely on the proposed Treasury Regulations until final regulations are issued.

Prospective investors are encouraged to consult with their own tax advisors regarding the possible implications of this legislation on their investment in our common stock.

## UNDERWRITING

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

<u>Name</u>	<u>Number of Shares</u>
Morgan Stanley & Co. LLC	7,280,000
Jefferies LLC	5,460,000
Stifel, Nicolaus & Company, Incorporated	3,094,000
Guggenheim Securities, LLC	2,366,000
Total	<u>18,200,000</u>

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

The underwriters initially propose to offer part of the shares of common stock directly to the public at the offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$0.714 per share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to 2,730,000 additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter’s name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table.

The following table shows the per share and total public offering price, underwriting discounts and commissions, and proceeds before expenses to us. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase up to an additional 2,730,000 shares of common stock.

	<u>Per Share</u>	<u>Total</u>	
		<u>No Exercise</u>	<u>Full Exercise</u>
Public offering price	\$ 17.00	\$ 309,400,000	\$ 355,810,000
Underwriting discounts and commissions to be paid by us	\$ 1.19	\$ 21,658,000	\$ 24,906,700
Proceeds, before expenses, to us	\$ 15.81	\$ 287,742,000	\$ 330,903,300

## Table of Contents

The estimated offering expenses payable by us, exclusive of the underwriting discounts and commissions, are approximately \$3.8 million. We have agreed to reimburse the underwriters for expense relating to clearance of this offering with the Financial Industry Regulatory Authority up to \$35,000.

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

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

We and all directors and officers and the holders of approximately 100% of our outstanding stock and stock options have agreed that, without the prior written consent of Morgan Stanley & Co. LLC and Jefferies LLC, on behalf of the underwriters, we and they will not, and will not publicly disclose an intention to, during the period ending 180 days after the date of this prospectus (the “restricted period”):

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

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

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

- transactions relating to shares of common stock or other securities acquired in this offering or in open market transactions after the completion of this offering; provided, with respect to our directors, officers and certain of our holders, that no filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made during the restricted period in connection with subsequent sales of common stock or other securities acquired in this offering or in such open market transactions;
- transfers or distributions of shares of common stock or any security convertible into or exercisable or exchangeable for common stock (i) as a bona fide gift or charitable contribution, (ii) by will or intestacy or to any immediate family member or to a trust for the direct or indirect benefit of such person and/or any immediate family member of such person, (iii) to general or limited partners, members or stockholders, or holders of similar equity interests, of such person, (iv) in certain cases, if such person is an entity, to partners, members, shareholders, beneficiaries or holders of similar equity interests in such person, or to the estate of any such partners, members, shareholders beneficiaries or holders of similar equity interests or (v) to another corporation, partnership, limited liability company, trust or other business entity, including the subsidiaries of such person, that is a direct or indirect affiliate (as defined in Rule 405 promulgated under the Securities Act of 1933, as amended) of such person, or to any investment fund or other entity that controls or manages, is controlled or managed by or is under common control or common management with such person or affiliates of such person; *provided* that (A) each transferee or distributee shall sign and deliver a lock-up agreement substantially in the form of this agreement and (B) no filing under Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of common stock, shall be required or shall be voluntarily



## Table of Contents

made during the restricted period (other than, in certain cases of a transfer or distribution pursuant to clause (iii) or (v) above, any Form 5 required to be filed under the Exchange Act following the restricted period if such person is subject to Section 16 reporting with respect to the company under the Exchange Act and indicating by footnote disclosure or otherwise the nature of the transfer or distribution);

- facilitating the establishment of a trading plan on behalf of a stockholder, officer or director of the company pursuant to Rule 10b5-1 under the Exchange Act for the transfer of shares of common stock; provided that (i) such plan does not provide for the transfer of common stock during the restricted period and (ii) to the extent a public announcement or filing under the Exchange Act, if any, is required of or voluntarily made by or on behalf of such person or the company regarding the establishment of such plan, such announcement or filing shall include a statement to the effect that no transfer of common stock may be made under such plan during the restricted period;
- transfers of common stock or any security convertible into or exercisable or exchangeable for common stock by operation of law pursuant to a qualified domestic order or other court order or in connection with a divorce settlement; provided that (i) no filing under Section 16(a) of the Exchange Act or any other public filing or disclosure shall be voluntarily made during the restricted period, and any required filing shall clearly indicate in the footnotes thereto that (A) the filing relates to the circumstances described herein and (B) no securities were sold by such person, and (ii) such person does not otherwise voluntarily effect any other public filing or report regarding such transfers during the restricted period;
- the receipt by such person from the company of shares of common stock upon the transfer or disposition of shares of common stock or any securities convertible into common stock to the company upon a vesting or settlement event of the company's securities or vesting of restricted stock unit awards or upon the exercise of options to purchase the company's securities on a "cashless" or "net exercise" basis, in each case pursuant to any equity incentive plan of the company described in this prospectus and to the extent permitted by the instruments representing such restricted stock unit awards or options outstanding as of the date hereof (and solely to cover the exercise price or withholding tax obligations in connection with such transaction and any transfer to the company for the payment of the exercise price or taxes as a result of such transaction); provided that (i) the shares received upon exercise or settlement of the option are subject to the terms of the lock-up agreement, (ii) no public disclosure or filing under Section 16(a) of the Exchange Act shall be voluntarily made during the restricted period and (iii) to the extent a filing under Section 16(a) of the Exchange Act is required during the restricted period as a result of transfers described herein, it shall clearly indicate that (A) the filing relates to the circumstances described herein, including that the securities remain subject to the terms of a lock-up agreement and (B) no securities were sold by such person other than as contemplated hereby;
- transfers to the company in connection with the repurchase of common stock in connection with the termination of such person's employment with the company pursuant to contractual agreements with the company as in effect as of the date hereof and (in certain cases) disclosed to Morgan Stanley & Co. LLC and Jefferies LLC; provided that no public disclosure or filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made during the restricted period;
- the conversion of the outstanding preferred stock of the company described in this prospectus into shares of common stock of the company; provided that such shares of common stock remain subject to the terms of the lock-up agreement; or
- transfers pursuant to a bona fide third-party tender offer, merger, consolidation or other similar transaction approved by the company's board of directors and made to all holders of the company's securities involving a change of control of the company (including, without limitation, the entering into any lock-up, voting or similar agreement pursuant to which such person may agree to transfer, sell, tender or otherwise dispose of common stock or other such securities in connection with such transaction, or vote any common stock or other such securities in favor of any such transaction);

## **Table of Contents**

provided that in the event that such tender offer, merger, consolidation or other such transaction is not completed, such securities held by such person shall remain subject to the provisions of the lock-up agreement. The lock-ups of certain significant shareholders are subject to a pro rata release.

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

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

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

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

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

In addition, in the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investment and securities activities may involve our securities and instruments. The underwriters and their respective affiliates may also make investment recommendations or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long or short positions in such securities and instruments.

### **Pricing of the Offering**

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

## **Selling Restrictions**

### ***European Economic Area***

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

- (a) to any legal entity which is a qualified investor as defined in the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined in the Prospectus Regulation), subject to obtaining the prior consent of the representatives; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any of our representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with each of the representatives and us that it is a “qualified investor” as defined in the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5 of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged, and agreed that the shares acquired by it in the offer have not been acquired on a nondiscretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer of any shares to the public other than their offer or resale in a Member State to qualified investors as so defined or in circumstances in which the prior consent of the representatives has been obtained to each such proposed offer or resale.

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

### ***United Kingdom***

In relation to the United Kingdom, no securities have been offered or will be offered pursuant to this offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the securities that either (i) has been approved by the Financial Conduct Authority, or (ii) is to be treated as if it had been approved by the Financial Conduct Authority in accordance with the transitional provision in Regulation 74 of the Prospectus (Amendment etc.) (EU Exit) Regulations 2019, except that offers of securities may be made to the public in the United Kingdom at any time under the following exemptions under the UK Prospectus Regulation:

- (a) to any legal entity which is a qualified investor as defined in Article 2 of the UK Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined in Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within section 86 of the Financial Services and Markets Act 2000, as amended, or the FSMA,

## Table of Contents

provided that no such offer of shares shall require the issuer or any underwriter to publish a prospectus pursuant to section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

For the purposes of this provision, the expression an “offer of shares to the public” in relation to any shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Each underwriter has represented and agreed that:

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

### **Canada**

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

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

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

### **Japan**

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

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

## Table of Contents

### ***For Qualified Institutional Investors (“QII”)***

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

### ***For Non-QII Investors***

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

### ***Hong Kong***

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

### ***Singapore***

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of shares of our common stock may not be circulated or distributed, nor may the shares of our common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor (as defined under Section 4A of the Securities and Futures Act, Chapter 289 of Singapore (the “SFA”)) under Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to conditions set forth in the SFA.

Where shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor, the securities (as defined in Section 239(1) of the SFA) of that corporation shall not be transferable for six months after that corporation has acquired shares of our common

## Table of Contents

stock under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer in that corporation's securities pursuant to Section 275(1A) of the SFA, (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore ("Regulation 32").

Where shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is a trust (where the trustee is not an accredited investor (as defined in Section 4A of the SFA)) whose sole purpose is to hold investments and each beneficiary of the trust is an accredited investor, the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferable for 6 months after that trust has acquired shares of our common stock under Section 275 of the SFA except: (1) to an institutional investor under Section 274 of the SFA or to a relevant person (as defined in Section 275(2) of the SFA), (2) where such transfer arises from an offer that is made on terms that such rights or interest are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction (whether such amount is to be paid for in cash or by exchange of securities or other assets), (3) where no consideration is or will be given for the transfer, (4) where the transfer is by operation of law, (5) as specified in Section 276(7) of the SFA, or (6) as specified in Regulation 32.

*Solely for purposes of the notification requirements under Section 309B(1)(c) of the Securities and Futures Act, Chapter 289 of Singapore, the shares of our common stock are "prescribed capital markets products" (as defined in the Securities and Futures (Capital Markets Products) Regulations 2018) and Excluded Investment Products (as defined in MAS Notice SFA 04-N12: Notice on the Sale of Investment Products and MAS Notice FAA-N16: Notice on Recommendations on Investment Products).*

### **Australia**

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission ("ASIC"), in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the "Corporations Act"), and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the "Exempt Investors") who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

***Israel***

In the State of Israel this prospectus shall not be regarded as an offer to the public to purchase shares of common stock under the Israeli Securities Law, 5728 – 1968, which requires a prospectus to be published and authorized by the Israel Securities Authority, if it complies with certain provisions of Section 15 of the Israeli Securities Law, 5728 – 1968, including, inter alia, if: (i) the offer is made, distributed or directed to not more than 35 investors, subject to certain conditions (the “Addressed Investors”); or (ii) the offer is made, distributed or directed to certain qualified investors defined in the First Addendum of the Israeli Securities Law, 5728 – 1968, subject to certain conditions (the “Qualified Investors”). The Qualified Investors shall not be taken into account in the count of the Addressed Investors and may be offered to purchase securities in addition to the 35 Addressed Investors. The company has not and will not take any action that would require it to publish a prospectus in accordance with and subject to the Israeli Securities Law, 5728 – 1968. We have not and will not distribute this prospectus or make, distribute or direct an offer to subscribe for our common stock to any person within the State of Israel, other than to Qualified Investors and up to 35 Addressed Investors.

Qualified Investors may have to submit written evidence that they meet the definitions set out in of the First Addendum to the Israeli Securities Law, 5728 – 1968. In particular, we may request, as a condition to be offered common stock, that Qualified Investors will each represent, warrant and certify to us and/or to anyone acting on our behalf: (i) that it is an investor falling within one of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968; (ii) which of the categories listed in the First Addendum to the Israeli Securities Law, 5728 – 1968 regarding Qualified Investors is applicable to it; (iii) that it will abide by all provisions set forth in the Israeli Securities Law, 5728 – 1968 and the regulations promulgated thereunder in connection with the offer to be issued common stock; (iv) that the shares of common stock that it will be issued are, subject to exemptions available under the Israeli Securities Law, 5728 – 1968: (a) for its own account; (b) for investment purposes only; and (c) not issued with a view to resale within the State of Israel, other than in accordance with the provisions of the Israeli Securities Law, 5728 – 1968; and (v) that it is willing to provide further evidence of its Qualified Investor status. Addressed Investors may have to submit written evidence in respect of their identity and may have to sign and submit a declaration containing, inter alia, the Addressed Investor’s name, address and passport number or Israeli identification number.

***Switzerland***

This document is not intended to constitute an offer or solicitation to purchase or invest in the securities. The securities may not be publicly offered, directly or indirectly, in Switzerland within the meaning of the Swiss Financial Services Act (“FinSA”) and no application has or will be made to admit the securities to trading on any trading venue (exchange or multilateral trading facility) in Switzerland. Neither this document nor any other offering or marketing material relating to the securities constitutes a prospectus pursuant to the FinSA, and neither this document nor any other offering or marketing material relating to the securities may be publicly distributed or otherwise made publicly available in Switzerland.

## LEGAL MATTERS

The validity of the shares of common stock offered hereby will be passed upon for us by Cooley LLP, New York, New York. Certain legal matters will be passed upon for the underwriters by Davis Polk & Wardwell LLP, New York, New York. As of the date of this prospectus, GC&H Investments, L.P. and GC&H Investments A1, L.P., entities consisting of current and former partners and associates of Cooley LLP, collectively beneficially hold an aggregate of 64,030 shares of our common stock on an as-converted basis.

## EXPERTS

The financial statements as of December 31, 2020 and for the period from June 3, 2020 (inception) to December 31, 2020 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 to the consolidated financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock being offered by this prospectus. This prospectus, which constitutes part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to our company and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the internet at the SEC's website at [www.sec.gov](http://www.sec.gov). Upon completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available at [www.sec.gov](http://www.sec.gov).

We also maintain a website at [adagiotx.com](http://adagiotx.com), at which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated into, this prospectus. We have included our website in this prospectus solely as an inactive textual reference.



INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Consolidated Balance Sheets</a>	F-3
<a href="#">Consolidated Statements of Operations and Comprehensive Loss</a>	F-4
<a href="#">Consolidated Statements of Convertible Preferred Stock and Stockholders' Deficit</a>	F-5
<a href="#">Consolidated Statements of Cash Flows</a>	F-7
<a href="#">Notes to Consolidated Financial Statements</a>	F-8

**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 sheet of Adagio Therapeutics, Inc. and its subsidiary (the “Company”) as of December 31, 2020, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders’ deficit and of cash flows 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, 2020, and the results of its operations and its cash flows for the period from June 3, 2020 (inception) to December 31, 2020 in conformity with accounting principles generally accepted in the United States of America.

***Substantial Doubt about the Company’s Ability to Continue as a Going Concern***

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred recurring losses from operations since inception, expects to continue to generate operating losses for the foreseeable future and will require additional capital to finance its future operations. These conditions raise substantial doubt about the Company’s ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

***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 audit. 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 audit of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

May 21, 2021, except for the effects of the stock split discussed in Note 15 to the consolidated financial statements, as to which the date is August 2, 2021

We have served as the Company’s auditor since 2021.

**ADAGIO THERAPEUTICS, INC.**  
**CONSOLIDATED BALANCE SHEETS**  
(In thousands, except share and per share amounts)

	<u>December 31,</u> <u>2020</u>	<u>March 31,</u> <u>2021</u> (unaudited)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 114,988	\$ 91,247
Prepaid expenses and other current assets	2,394	3,627
Total current assets	<u>117,382</u>	<u>94,874</u>
Total assets	<u>\$ 117,382</u>	<u>\$ 94,874</u>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 8,153	\$ 11,317
Accrued expenses	4,919	17,360
Total current liabilities	<u>13,072</u>	<u>28,677</u>
Early-exercise liability	11	11
Total liabilities	<u>13,083</u>	<u>28,688</u>
Commitments and contingencies (Note 7)		
Series A convertible preferred stock, \$0.0001 par value; 11,237,500 shares authorized, issued and outstanding as of December 31, 2020 and March 31, 2021 (unaudited); liquidation preference of \$89,900 as of December 31, 2020 and March 31, 2021 (unaudited)	<u>89,706</u>	<u>89,706</u>
Series B convertible preferred stock, \$0.0001 par value; 1,410,434 shares authorized, issued and outstanding as of December 31, 2020 and March 31, 2021 (unaudited); liquidation preference of \$80,000 as of December 31, 2020 and March 31, 2021 (unaudited)	<u>79,842</u>	<u>79,842</u>
Stockholders' deficit:		
Common stock, \$0.0001 par value; 150,000,000 shares authorized, 28,193,240 shares issued and 5,593,240 shares outstanding as of December 31, 2020 and March 31, 2021 (unaudited)	1	1
Treasury stock, at cost; 22,600,000 shares	(85)	(85)
Additional paid-in capital	154	741
Accumulated deficit	<u>(65,319)</u>	<u>(104,019)</u>
Total stockholders' deficit	<u>(65,249)</u>	<u>(103,362)</u>
Total liabilities, convertible preferred stock and stockholders' deficit	<u>\$ 117,382</u>	<u>\$ 94,874</u>

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)**

	<u>Period from June 3, 2020 (Inception) to December 31, 2020</u>	<u>Three Months Ended March 31, 2021 (unaudited)</u>
Operating expenses:		
Research and development <sup>(1)</sup>	\$ 21,992	\$ 34,032
Acquired in-process research and development <sup>(2)</sup>	40,125	1,000
Selling, general and administrative	3,210	3,677
Total operating expenses	<u>65,327</u>	<u>38,709</u>
Loss from operations	<u>(65,327)</u>	<u>(38,709)</u>
Other income:		
Interest income	8	9
Total other income	<u>8</u>	<u>9</u>
Net loss and comprehensive loss	<u>\$ (65,319)</u>	<u>\$ (38,700)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (18.10)</u>	<u>\$ —</u>
Weighted-average common shares outstanding, basic and diluted	<u>3,608,491</u>	<u>—</u>

(1) Includes related-party amounts of \$595 for the period from June 3, 2020 (inception) to December 31, 2020 and \$188 for the three months ended March 31, 2021 (see Note 6).

(2) Includes related-party amounts of \$39,915 for the period from June 3, 2020 (inception) to December 31, 2020 and \$1,000 for the three months ended March 31, 2021 (see Note 6).

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

## ADAGIO THERAPEUTICS, INC.

## CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(In thousands, except share amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balances at June 3, 2020 (Inception)</b>	—	\$ —	—	\$ —	—	\$ —	—	\$ —	\$ —	\$ —	\$ —
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)
<b>Balances at December 31, 2020</b>	<u>11,237,500</u>	<u>\$89,706</u>	<u>1,410,434</u>	<u>\$79,842</u>	<u>5,593,240</u>	<u>\$ 1</u>	<u>22,600,000</u>	<u>\$ (85)</u>	<u>\$ 154</u>	<u>\$ (65,319)</u>	<u>\$ (65,249)</u>

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

ADAGIO THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT

(In thousands, except share amounts)

	Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
<b>Balances at December 31, 2020</b>	11,237,500	\$89,706	1,410,434	\$79,842	5,593,240	\$ 1	22,600,000	\$ (85)	\$ 154	\$ (65,319)	\$ (65,249)
Stock-based compensation expense (unaudited)	—	—	—	—	—	—	—	—	587	—	587
Net loss (unaudited)	—	—	—	—	—	—	—	—	—	(38,700)	(38,700)
<b>Balances at March 31, 2021 (unaudited)</b>	<u>11,237,500</u>	<u>\$89,706</u>	<u>1,410,434</u>	<u>\$79,842</u>	<u>5,593,240</u>	<u>\$ 1</u>	<u>22,600,000</u>	<u>\$ (85)</u>	<u>\$ 741</u>	<u>\$ (104,019)</u>	<u>\$ (103,362)</u>

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

**ADAGIO THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(In thousands)**

	<b>Period from June 3, 2020 (Inception) to December 31, 2020</b>	<b>Three Months Ended March 31, 2021 (unaudited)</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (65,319)	\$ (38,700)
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	155	587
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(2,394)	(1,178)
Accounts payable	8,153	3,164
Accrued expenses	4,919	12,386
Net cash used in operating activities	<u>(14,571)</u>	<u>(23,741)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of convertible preferred stock, net of issuance costs	129,548	—
Proceeds from early exercises of stock options	14	—
Payments for repurchases of restricted common stock	(3)	—
Net cash provided by financing activities	<u>129,559</u>	<u>—</u>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>114,988</b>	<b>(23,741)</b>
Cash and cash equivalents at beginning of period	—	114,988
Cash and cash equivalents at end of period	<u>\$ 114,988</u>	<u>\$ 91,247</u>
<b>Supplemental disclosure of non-cash financing activities:</b>		
Deferred offering costs included in accrued expenses	\$ —	\$ 55
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.

**ADAGIO THERAPEUTICS, INC.**  
**NOTES TO 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 antibody-based solutions for infectious diseases with pandemic potential. The Company’s initial focus is on the virus SARS-CoV-2, its variants and the disease caused by this virus, which is known as Coronavirus Infectious Disease (“COVID-19”). The Company initiated clinical trials for its lead product candidate, ADG20, in February 2021. The Company was incorporated in the State of Delaware in June 2020. The Company operates as a virtual company and, thus, does not maintain a corporate headquarters or other significant facilities. In addition, the Company engages third parties, including Adimab, LLC (“Adimab”), to perform ongoing research and development and other services on its behalf.

In July 2020, the Company entered into an assignment and license agreement with Adimab pursuant to which it acquired certain rights to Adimab’s antibodies relating to COVID-19 and severe acute respiratory syndrome (“SARS”) as well as related provisional patent applications, know-how and data generated with respect to the associated antibodies. In addition, Adimab granted to the Company a non-exclusive, worldwide license to certain of Adimab’s platform patents and technology for use in research and development. In connection with the transfer of the rights acquired and license received, the Company issued 5,000,000 shares of its Series A convertible preferred stock to Adimab (see Note 6). As of December 31, 2020 and March 31, 2021 (unaudited), Adimab, a related party, held approximately 39.5% of the Company’s outstanding capital stock.

The Company is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, completing preclinical studies and 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 the COVID-19 coronavirus, dependence on key personnel, the ability to attract and retain qualified employees, reliance on third-party organizations and the clinical and commercial success of its product candidates.

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 in conformity with accounting principles generally accepted in the United States of America (“GAAP”) and 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.

***Going Concern***

The Company has evaluated whether there are certain conditions and events, considered in the aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

Through December 31, 2020 and March 31, 2021 (unaudited), the Company has funded its operations with proceeds from sales of its convertible preferred stock. The Company has incurred recurring losses since its



**ADAGIO THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

inception, including net losses of \$65.3 million for the period from June 3, 2020 (inception) to December 31, 2020 and \$38.7 million for the three months ended March 31, 2021 (unaudited). In addition, as of December 31, 2020 and March 31, 2021 (unaudited), the Company had an accumulated deficit of \$65.3 million and \$104.0 million, respectively. The Company expects to continue to generate significant operating losses for the foreseeable future. As of May 21, 2021, the issuance date of the consolidated financial statements for the period from June 3, 2020 (inception) to December 31, 2020 and of the interim consolidated financial statements for the three months ended March 31, 2021, the Company expects that its existing cash and cash equivalents, including the \$335.5 million of gross proceeds it received from the issuance and sale of its Series C convertible preferred stock in April 2021 (see Note 15), will be sufficient to fund its operating expenses and capital expenditure requirements through March 31, 2022. The future viability of the Company beyond that point is dependent on its ability to raise additional capital to finance its operations.

The Company is seeking to complete an initial public offering (“IPO”) of its common stock. Upon the closing of a qualifying public offering on specified terms, the Company’s outstanding convertible preferred stock will automatically convert into common stock (see Notes 8 and 15).

In the event the Company does not complete an IPO, the Company expects to seek additional funding through private equity financings, 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.

Based on its recurring losses from operations incurred since inception, expectation of continuing operating losses for the foreseeable future, and the need to raise additional capital to finance its future operations, as of May 21, 2021, the issuance date of the consolidated financial statements for the period from June 3, 2020 (inception) to December 31, 2020 and of the interim consolidated financial statements for the three months ended March 31, 2021, the Company has concluded that there is substantial doubt about its ability to continue as a going concern for a period of one year from the date that these consolidated financial statements are issued.

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

***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 ADG20 for the treatment and prevention of COVID-19. The severity of the COVID-19 pandemic and the

**ADAGIO THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

continued emergence of variants of concern, the availability, administration and acceptance of vaccines and monoclonal antibodies 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, such as travel, has fallen. 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 the outbreak and its impact on the Company’s clinical trial design and enrollment, trial sites, contract research organizations, contract manufacturing organizations and other third parties with which it does business, as well as its impact on regulatory authorities and the Company’s key scientific and management personnel. To date, the Company has not experienced significant delays or disruptions in its development activities as a result of the COVID-19 pandemic but may in the future as the outbreak progresses and some of its contract research organizations, contract manufacturing organizations and other service providers continue to be impacted. The Company will continue to monitor developments as it addresses 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 may materially adversely affect the Company’s results and operations and its ability to raise capital.

**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 and 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 May 21, 2021, the issuance date of these consolidated financial statements. These estimates may change as new events occur and additional information is obtained.

*Unaudited Interim Financial Information*

The accompanying consolidated balance sheet as of March 31, 2021 and the consolidated statements of operations and comprehensive loss, of cash flows and of convertible preferred stock and stockholders’ deficit for

**ADAGIO THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

the three months ended March 31, 2021 are unaudited. The unaudited interim consolidated financial statements have been prepared on the same basis as the audited consolidated financial statements for the period from June 3, 2020 (inception) to December 31, 2020 and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of March 31, 2021 and the results of its operations and its cash flows for the three months ended March 31, 2021. The financial data and other information disclosed in these notes related to the three months ended March 31, 2021 are also unaudited. The results for the three months ended March 31, 2021 are not necessarily indicative of results to be expected for the year ending December 31, 2021, any other interim periods, or any future year or period.

***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' 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. The Company had no deferred offering costs recorded as of December 31, 2020. As of March 31, 2021 (unaudited), the Company had deferred offering costs totaling \$0.1 million.

***Concentrations of Credit Risk, Significant Suppliers and License Rights***

Financial instruments that potentially expose the Company to concentrations of credit risk consist of cash and cash equivalents. The Company invests its excess cash in money market funds that are subject to minimal credit and market risks. The Company maintains its cash and cash equivalents at one accredited financial institution that it believes is 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 and cash equivalents 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, ADG20, and to manufacture supply of its current product candidate for preclinical and clinical activities (see Note 7). The Company also currently relies on this same third-party contract manufacturer for any anticipated requirements of commercial supply. 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, 2020 and March 31, 2021 (unaudited), the Company's research and development programs primarily relate to rights conveyed by Adimab (see Note 6). The Company could experience delays in the development and potential commercialization of its product candidates and programs if the Adimab license arrangement or any other license agreement utilized in the Company's research and development activities is

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.

***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 are carried at fair value, determined according to the fair value hierarchy described above (see Note 3). 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.

***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

**ADAGIO THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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 6), 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 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 6). Acquired IPR&D expense recognized for the three months ended March 31, 2021 consisted solely of the payment due for a milestone achieved under the Adimab arrangement (see Note 6).

***Classification and Accretion of Convertible Preferred Stock***

The Company's convertible preferred stock is classified outside of stockholders' deficit on the consolidated balance sheets because the holders of such shares have liquidation rights in the event of a deemed liquidation that, in certain situations, is not solely within the control of the Company and would require the redemption of the then-outstanding convertible preferred stock. The Company's Series A and Series B convertible preferred

**ADAGIO THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

stock are not redeemable, except in the event of deemed liquidation (see Note 8). Because the occurrence of a deemed liquidation event is not currently probable, the carrying values of the convertible preferred stock are not being accreted to their redemption values. Subsequent adjustments to the carrying values of the convertible preferred stock would be made only when a deemed liquidation event becomes probable.

***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, 2020 and March 31, 2021 (unaudited).

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, 2020 and March 31, 2021 (unaudited).

**ADAGIO THERAPEUTICS, INC.**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

***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. There was no difference between net loss and comprehensive loss for each of the periods presented in the accompanying consolidated financial statements.

***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.

***Recently Adopted Accounting Pronouncements***

In July 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480) and Derivatives and Hedging (Topic 815): I. Accounting for Certain Financial Instruments with Down Round Features and II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). Part I of this update addresses the complexity of accounting for certain financial instruments with down round features. Down round features are features of certain equity-linked instruments (or embedded features) that result in the strike price being reduced on the basis of the pricing of future equity offerings. Current accounting guidance creates cost and complexity for entities that issue financial instruments

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(such as warrants and convertible instruments) with down round features that require fair value measurement of the entire instrument or conversion option. Pursuant to the amendments in Part I of this update, when determining whether certain financial instruments should be classified as liabilities or equity instruments, a down round feature no longer precludes equity classification when assessing whether the instrument is indexed to an entity's own stock. Part II of this update replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of nonpublic entities contained within ASC No. 480 with a scope exception. The amendments in Part II of this update do not have an accounting effect. For public entities, ASU 2017-11 was required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. For nonpublic entities, ASU 2017-11 is effective for annual periods beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption was permitted. The Company adopted ASU 2017-11 on June 3, 2020 (inception) and the adoption did not have a material impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* ("ASU 2018-07"). ASU 2018-07 is intended to simplify several aspects of the accounting for non-employee share-based payment transactions. ASU 2018-07 expands the scope of ASC 718 to include share-based payments issued to non-employees for goods and services. Under ASU 2018-07, entities should apply the requirements of ASC 718 to non-employee awards except for specific guidance on inputs to an option pricing model and the attribution of compensation cost. Accordingly, the accounting for share-based payments to employees and non-employees will be substantially aligned based on this update. The cost of non-employee awards is recorded as if the grantor had paid cash for the goods or services. For public entities, ASU 2018-07 was required to be adopted for annual periods beginning after December 15, 2018, including interim periods within those fiscal years. For nonpublic entities, ASU 2018-07 is effective for annual periods beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted. The Company adopted ASU 2018-07 on June 3, 2020 (inception) and the adoption did not have a material impact on the Company's consolidated financial statements.

**Recently Issued Accounting Pronouncements**

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.

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



ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 is currently evaluating the potential impact that the adoption of this standard may have on its 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 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

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 is currently evaluating the potential impact that the adoption of this standard may have 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 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

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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. 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, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market fund	\$39,006	\$ —	\$ —	\$39,006
	<u>\$39,006</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$39,006</u>

	Fair Value Measurements at March 31, 2021 (unaudited) Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market fund	\$15,274	\$ —	\$ —	\$15,274
	<u>\$15,274</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$15,274</u>

The money market fund was valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy. There were no changes to the valuation methods for the period from June 3, 2020 (inception) to December 31, 2020 and for the three months ended March 31, 2021 (unaudited). The Company evaluates transfers between levels at the end of each reporting period. There were no transfers between Level 1 or Level 2 during the period from June 3, 2020 (inception) to December 31, 2020 and the three months ended March 31, 2021 (unaudited).

**4. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31, 2020	March 31, 2021 (unaudited)
Prepaid external research, development and manufacturing costs	\$ 2,253	\$ 3,070
Other	141	557
	<u>\$ 2,394</u>	<u>\$ 3,627</u>

## ADAGIO THERAPEUTICS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**5. Accrued Expenses**

Accrued expenses consisted of the following (in thousands):

	December 31, 2020	March 31, 2021 (unaudited)
Accrued external research, development and manufacturing costs	\$ 3,853	\$ 15,774
Accrued professional and consultant fees	237	1,084
Accrued employee compensation	794	485
Other	35	17
	<u>\$ 4,919</u>	<u>\$ 17,360</u>

**6. License 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

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 clinical trial evaluating ADG20, 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 clinical trial evaluating ADG20 for the prevention of COVID-19, which obligated the Company to make a \$2.5 million milestone payment. The Company recognized the expense related to the expected achievement of the second milestone in early April, when certain Phase 1 clinical trial data was submitted to the FDA for review and the second milestone under the agreement became probable of achievement. The next potential milestone payment that the Company may be obligated to make under the agreement is a \$4.0 million milestone payment for the first dosing of the first subject in the first Phase 3 clinical trial of a Product.

The Company is also 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, which was paid by the Company to Adimab in March 2021, no other milestone, royalty or other contingent payments had become due to Adimab through December 31, 2020 or March 31, 2021 (unaudited).

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 was recognized as acquired in-process research and development expense. For the period from June 3, 2020 (inception) to December 31, 2020 and for the three months ended March 31, 2021 (unaudited), the Company recognized \$39.9 million and \$1.0 million, respectively, as IPR&D expense in connection with upfront consideration and contingent consideration payable under the Adimab Assignment Agreement. 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

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.

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 period from June 3, 2020 (inception) to December 31, 2020 and for the three months ended March 31, 2021 (unaudited), the Company recognized \$0.6 million and \$0.2 million, respectively, of expense in connection with services provided by Adimab.

***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 March 31, 2021 (unaudited). 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, 2020 and March 31, 2021 (unaudited), 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

**ADAGIO THERAPEUTICS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

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.

**7. Commitments and Contingencies*****License Agreements***

The Company has entered into license agreements with Adimab and WuXi (see Note 6).

***Manufacturing Agreements***

In December 2020, the Company entered into a Commercial Manufacturing Services Agreement with WuXi (the “Commercial Manufacturing Agreement”). The Commercial Manufacturing Agreement outlines the terms and conditions under which WuXi will manufacture ADG20 drug substance for commercial use.

As of December 31, 2020 and March 31, 2021 (unaudited), the Company committed to minimum non-cancelable purchase obligations of \$142.4 million related to batches of ADG20 drug substance and \$0.5 million related to certain services with respect to the product requirements for 2021 and 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, 2020 are expected to be as follows (in thousands):

<b><u>Year Ending December 31,</u></b>	
2021	\$ 21,799
2022	66,972
2023	54,094
	<u>\$ 142,865</u>

As of December 31, 2020 and March 31, 2021 (unaudited), the Company had neither made any payments under the Commercial Manufacturing Agreement nor made any incremental purchases under the Commercial Manufacturing Agreement.

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.

***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 minimum purchase commitments. Certain of these agreements provide for termination rights subject to the payment of termination fees and/or wind-down

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.

***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, 2020 and March 31, 2021 (unaudited), 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. The Company has not incurred any material costs as a result of such indemnifications and is not currently aware of any indemnification claims.

**8. Convertible Preferred Stock**

The Company has issued Series A Preferred Stock and Series B convertible preferred stock (the “Series B Preferred Stock” and, together with the Series A Preferred Stock, 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 6).

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. 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.

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.



## ADAGIO THERAPEUTICS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In April 2021, the Company issued and sold 4,296,550 shares of Series C convertible preferred stock, at a purchase price of \$78.08578 per share, for aggregate gross proceeds of \$335.5 million (see Note 15).

At the balance sheet dates, Preferred Stock consisted of the following (in thousands, except share amounts):

	December 31, 2020 and March 31, 2021 (unaudited)				Common Stock Issuable Upon Conversion
	Shares Authorized	Shares Issued and Outstanding	Carrying Value	Liquidation Preference	
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
	<u>12,647,934</u>	<u>12,647,934</u>	<u>\$ 169,548</u>	<u>\$ 169,900</u>	<u>63,239,670</u>

The holders of Preferred Stock have the following rights and preferences:

**Voting**

The holders of the Preferred Stock are entitled to vote, together with the holders of common stock, on matters submitted to stockholders for a vote. Each holder of Preferred Stock is entitled to the number of votes equal to the number of whole shares of common stock into which the shares of Preferred Stock held by such holder is convertible as of the record date for determination of stockholders entitled to vote. The holders of Preferred Stock vote together with the holders of common stock as a single class on an as-converted basis. At any time when there are at least 2,250,000 shares of Series A Preferred Stock or at least 300,000 shares of Series B Preferred Stock (in each case, subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization) outstanding, certain actions such as mergers, acquisition, liquidation, dissolution, winding-up of the business, and deemed liquidation events, must be approved by a majority in voting power of the outstanding shares of Preferred Stock, voting as a single class.

In addition, the holders of shares of Series A Preferred Stock, voting exclusively and as a separate class, are entitled to elect four directors of the Company. The holders of shares of common stock and any other class or series of voting stock (including the Preferred Stock), exclusively and voting together as a single class, are entitled to elect the balance of the total number of directors of the Company.

**Conversion**

Each share of Preferred Stock is convertible at the option of the holder, at any time, and without the payment of additional consideration by the holder. In addition, each share of Preferred Stock will be automatically converted into shares of common stock at the then-effective applicable conversion ratio upon either (i) the closing of a firm commitment public offering of common stock at a price of at least \$17.02 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization), or (ii) the date specified by vote or written consent of the holders of a majority in voting power of the outstanding shares of Preferred Stock, voting as a single class.

The conversion ratio of each series of Preferred Stock is determined by dividing the Original Issue Price of each series by the Conversion Price of each series. The Original Issue Price is \$8.00 per share for the Series A Preferred Stock and \$56.72 per share for the Series B Preferred Stock. The Conversion Price is \$1.60 per share for the Series A Preferred Stock and \$11.344 per share for the Series B Preferred Stock (in each case subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization and other adjustments as set forth in the Company's certificate of incorporation, as amended and

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

restated). As of December 31, 2020 and March 31, 2021 (unaudited), each share of Preferred Stock was convertible into common stock on a five-for-one basis.

**Dividends**

The Company may not declare, pay or set aside any dividends on shares of any other class or series of capital stock (other than dividends on shares of common stock payable in shares of common stock) unless the holders of the Preferred Stock then outstanding first receive, or simultaneously receive, a dividend on each outstanding share of Preferred Stock in an amount at least equal to (i) in the case of a dividend being distributed to common stock or any class or series that is convertible into common stock, the equivalent dividend on an as-converted basis or (ii) in the case of a dividend being distributed on a class or series that is not convertible into common stock, a dividend equal to a dividend rate on each series of Preferred Stock calculated based on the respective Original Issue Price of each series of Preferred Stock. If the Company declares, pays or sets aside dividends on more than one class or series of capital stock, then the dividend payable to the holders of Preferred Stock will be calculated based on the dividend on the class or series of capital stock that would result in the highest dividend to the holders of Preferred Stock. Through December 31, 2020 and March 31, 2021 (unaudited), no dividends had been declared or paid by the Company.

**Liquidation**

In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, or upon the occurrence of a Deemed Liquidation Event (as defined below), the holders of shares of Preferred Stock then outstanding are entitled, on a *pari passu* basis, to be paid out of the assets or funds of the Company available for distribution to stockholders before any payment is made to the holders of common stock. The holders of Preferred Stock are entitled to an amount per share equal to the greater of (i) the applicable Original Issue Price of such series of Preferred Stock, plus any dividends declared but unpaid thereon, or (ii) the amount that would have been payable had all shares of each series of Preferred Stock been converted into common stock immediately prior to such liquidation, dissolution, winding up or Deemed Liquidation Event. If upon any such liquidation event, the assets or funds of the Company available for distribution to stockholders are insufficient to pay the holders of shares of Preferred Stock the full amount to which they are entitled, then the holders of shares of Preferred Stock will share ratably in any distribution of the assets or funds available for distribution in proportion to the respective amounts which would otherwise be payable if it were paid in full.

Unless (i) the holders of a majority in voting power of the outstanding shares of Preferred Stock and (ii) with respect to the Series B Preferred Stock only, the holders of at least 65% of the outstanding shares of Series B Preferred Stock, elect otherwise, a Deemed Liquidation Event shall include a merger, consolidation, or share exchange (other than one in which stockholders of the Company own a majority by voting power of the outstanding shares of the surviving or acquiring corporation) or a sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company.

**Redemption**

The Preferred Stock does not have redemption rights, except for the contingent redemption upon the occurrence of a Deemed Liquidation Event.

**9. 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

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

above. Each share of common stock entitles the holder to one vote for each share of common stock, together with the holders of Preferred Stock, on all matters submitted to the stockholders for a vote.

As of December 31, 2020 and March 31, 2021 (unaudited), 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 2020 Equity Incentive Plan.

***Treasury Stock***

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, 2020 and March 31, 2021 (unaudited), the 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' 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 6).

In April and May 2021, an aggregate of 22,600,000 shares of common stock held in treasury were retired (see Note 15).

**10. 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 number of shares of common stock initially reserved for issuances under the 2020 Plan was 9,926,470 shares. In October 2020, the Company's board of directors increased the number of shares of common stock reserved for issuance under the plan from 9,926,470 shares to 22,820,305 shares. Accordingly, there were a total of 22,820,305 shares of common stock authorized for issuance under the 2020 Plan at December 31, 2020 and March 31, 2021 (unaudited). Shares of unused common stock that cover awards that expire or lapse or are terminated, surrendered or canceled without having been fully exercised or are forfeited will again be available for the grant of awards under the 2020 Plan. As of December 31, 2020 and March 31, 2021 (unaudited), there were 14,258,995 shares and 11,860,995 shares, respectively, remaining available for future grant under the 2020 Plan.

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. The Company's board of directors determines the fair value 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

## ADAGIO THERAPEUTICS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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.

**Stock Option Valuation**

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. The Company historically has been a private company and lacks 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 fair value of stock options granted:

	Period from June 3, 2020 (Inception) to December 31, 2020	Three Months Ended March 31, 2021 (unaudited)
Fair value of common stock	\$ 0.31	\$ 4.61
Expected term (in years)	6.1	6.0
Expected volatility	72.3%	73.5%
Risk-free interest rate	0.4%	0.6%
Expected dividend yield	—%	—%

**ADAGIO THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**Stock Option Activity**

The following table summarizes the Company's stock option activity since June 3, 2020:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands) \$
Outstanding at June 3, 2020 (inception)	—	\$ —	—	\$ —
Granted	9,911,310	0.24		
Exercised	(6,943,240)	0.01		
Forfeited	—	—		
Outstanding at December 31, 2020	2,968,070	\$ 0.78	9.8	\$ 11,362
Granted (unaudited)	2,513,000	4.61		
Exercised (unaudited)	—	—		
Forfeited (unaudited)	(115,000)	4.61		
Outstanding at March 31, 2021 (unaudited)	5,366,070	\$ 2.49	9.6	\$ 31,495
Vested and expected to vest at December 31, 2020	2,968,070	\$ 0.78	9.8	\$ 11,362
Options exercisable at December 31, 2020	—	\$ —	—	\$ —
Vested and expected to vest at March 31, 2021 (unaudited)	5,366,070	\$ 2.49	9.6	\$ 31,495
Options exercisable at March 31, 2021 (unaudited)	—	\$ —	—	\$ —

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, 2020 and March 31, 2021 (unaudited), as applicable. 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 \$14,000.

The weighted-average grant date fair value of stock options granted during the period from June 3, 2020 (inception) to December 31, 2020 and for the three months ended March 31, 2021 (unaudited) was \$0.21 and \$2.95, respectively, per option.

**Early Exercise of Stock Options into Restricted Stock**

The Company's restricted stock activity during the period from June 3, 2020 (inception) to December 31, 2020 is solely due to shares of restricted common stock issued pursuant to the permitted 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.

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A summary of the Company's unvested common stock from option early exercises that is subject to repurchase by the Company is as follows:

	Number of Shares
Unvested restricted stock at June 3, 2020 (inception)	—
Issued	6,943,240
Vested	—
Repurchased	(1,350,000)
Unvested restricted stock at December 31, 2020	5,593,240
Issued (unaudited)	—
Vested (unaudited)	—
Repurchased (unaudited)	—
Unvested restricted stock at March 31, 2021 (unaudited)	<u>5,593,240</u>

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, 2020 and March 31, 2021 (unaudited), the liability related to the payments for unvested shares from early-exercised options was \$11,000 at each date.

In December 2020, the Company repurchased 1,350,000 shares of restricted common stock for \$2,700, which was recorded as a reduction of the early-exercise liability and as shares of treasury stock.

**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):

	Period from June 3, 2020 (Inception) to December 31, 2020	Three Months Ended March 31, 2021 (unaudited)
Research and development	\$ 125	\$ 279
Selling, general and administrative	30	308
	<u>\$ 155</u>	<u>\$ 587</u>

As of December 31, 2020, total unrecognized stock-based compensation cost related to unvested awards was \$1.9 million and the weighted-average period over which such expense is expected to be recognized is 3.5 years. As of March 31, 2021 (unaudited), total unrecognized stock-based compensation cost related to unvested awards was \$8.4 million and the weighted-average period over which such expense is expected to be recognized is 3.3 years.

## ADAGIO THERAPEUTICS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**11. Income Taxes**

During the period from June 3, 2020 (inception) to December 31, 2020 and three months ended March 31, 2021 (unaudited), 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.

In March 2020, the Coronavirus Aid, Relief, and Economic Security ("CARES") Act was enacted. Among the business provisions, the CARES Act provided for various payroll tax incentives, changes to net operating loss carryback and carryforward rules, business interest expense limitation increases, and bonus depreciation on qualified improvement property. The Company determined that the CARES Act did not have a significant impact on its provision for income taxes.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Period from June 3, 2020 (Inception) to December 31, 2020
Federal statutory income tax rate	(21.0)%
State income taxes, net of federal benefit	(0.4)
Federal and state research and development tax credits	(0.2)
Non-deductible IPR&D expense	12.9
Change in deferred tax asset valuation allowance	8.7
Effective income tax rate	<u>—%</u>

The Company's net deferred tax assets consisted of the following (in thousands):

	December 31, 2020
Deferred tax assets:	
Net operating loss carryforwards	\$ 5,340
Research and development tax credits carryforwards	138
Other	204
Total deferred tax assets	<u>5,682</u>
Deferred tax liabilities:	—
Total deferred tax liabilities	<u>—</u>
Valuation allowance	(5,682)
Net deferred tax assets	<u>\$ —</u>

As of December 31, 2020, the Company had U.S. federal net operating loss carryforwards of \$24.4 million, which may be available to reduce future taxable income. All of the U.S. federal net operating loss carryforwards 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, 2020, the Company had state net operating loss carryforwards of \$3.7 million, which may be available to reduce future taxable income, of which \$0.3 million have an indefinite carryforward period while the remaining \$3.4 million begin to expire in 2040. As of December 31, 2020, the Company also had U.S. federal and state research and development tax credit carryforwards of \$0.1 million and \$16,000, respectively, which may be available to reduce future tax liabilities

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

and expire at various dates beginning in 2040 and 2035, respectively.

Utilization of the U.S. federal and state net operating loss 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 net operating loss 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. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before their utilization. Further, until a study is completed by the Company and any limitation is known, no amounts are being presented as an uncertain tax position.

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, 2020 and March 31, 2021 (unaudited). Management reevaluates the positive and negative evidence at each reporting period. During the period from June 3, 2020 (inception) to December 31, 2020, the Company increased its valuation allowance by \$5.7 million, 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 the uncertainty in its income tax positions to determine whether a tax position of the Company is more likely than not to be sustained upon examination, including resolution of any related appeals or litigation processes, based on the technical merits of the position. For tax positions meeting the more-likely-than-not threshold, the tax amount recognized in the financial statements is reduced by the largest benefit that has a greater than 50% likelihood of being realized upon the ultimate settlement with the relevant taxing authority. As of December 31, 2020 and March 31, 2021 (unaudited), the Company had not recorded any reserves for 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 net operating loss 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.

## 12. 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



ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 period from June 3, 2020 (inception) to December 31, 2020 and the three months ended March 31, 2021 (unaudited), the Company made contributions of \$36,000 and \$0.1 million, respectively, to the 401(k) Plan.

**13. 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):

	<b>Period from June 3, 2020 (Inception) to December 31, 2020</b>
<b>Numerator:</b>	
Net loss attributable to common stockholders	\$ (65,319)
<b>Denominator:</b>	
Weighted-average common shares outstanding, basic and diluted	3,608,491
<b>Net loss per share attributable to common stockholders, basic and diluted</b>	<b>\$ (18.10)</b>

Net loss per share data is not applicable for the three months ended March 31, 2021 (unaudited) 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 December 31, 2020 and March 31, 2021 (unaudited) 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 period from June 3, 2020 (inception) to December 31, 2020 and for the three months ended March 31, 2021 (unaudited). For the period from June 3, 2020 (inception) to December 31, 2020, the 3,608,491 shares of common stock outstanding solely reflect the weighted-average period that 21,250,000 shares of common stock repurchased by the Company from Adimab (see Note 6) were outstanding during that period.

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:

	<b>Period from June 3, 2020 (Inception) to December 31, 2020</b>
Convertible preferred stock (as converted to common stock)	63,239,670
Stock options to purchase common stock	2,968,070
Unvested restricted common stock	5,593,240
	<u>71,800,980</u>

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

**14. Related Party Transactions**

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 6). As of December 31, 2020 and March 31, 2021 (unaudited), \$0.6 million and \$0.2 million, respectively, was due to Adimab by the Company. As of December 31, 2020 and March 31, 2021 (unaudited), no amounts were due from Adimab to the Company.

On May 21, 2021, the Company entered into a collaboration agreement with Adimab (see Note 15).

**15. Subsequent Events**

For its consolidated financial statements as of December 31, 2020 for the period from June 3, 2020 (inception) to December 31, 2020 and for its interim consolidated financial statements as of March 31, 2021 and for the three months then ended, the Company evaluated subsequent events through May 21, 2021, the date on which those financial statements were issued.

***Grant of Stock Options under the 2020 Plan***

In January 2021, the Company granted options for the purchase of an aggregate of 2,513,000 shares of common stock, at an exercise price of \$4.61 per share. In April 2021, the Company granted options for the purchase of an aggregate of 1,198,750 shares of common stock, at an exercise price of \$8.36 per share. On May 7, 2021, the Company granted options for the purchase of an aggregate of 6,341,740 shares of common stock, at an exercise price of \$10.14 per share. The aggregate grant-date fair value of the options granted under these three option grants was \$56.3 million, which is expected to be recognized as stock-based compensation expense over a weighted-average period of approximately 3.8 years.

***Milestone Achievements under the Adimab Assignment Agreement***

In February 2021, the Company dosed the first patient in a Phase 1 clinical trial evaluating ADG20, which resulted in a milestone payment of \$1.0 million being due by the Company under the Adimab Assignment Agreement. In March 2021, the Company made the \$1.0 million payment to Adimab.

In April 2021, the Company dosed the first patient in a Phase 2 clinical trial evaluating ADG20 for the prevention of COVID-19, which resulted in a milestone payment of \$2.5 million being due by the Company under the Adimab Assignment Agreement.

***Increase in Authorized Number of Shares of Common Stock and Preferred Stock***

In April 2021, the Company increased the number of shares of common stock authorized for issuance from 19,000,000 shares to 23,251,555 shares and increased the number of shares of preferred stock authorized for issuance from 12,647,934 shares to 16,944,484 shares, of which 4,296,550 shares were designated as Series C convertible preferred stock (the "Series C Preferred Stock").

***Increase in Shares Reserved for Issuance under the 2020 Plan***

In April 2021, the Company's board of directors increased the number of shares of common stock reserved for issuance under the plan from 22,820,305 shares to 29,254,790 shares.

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

***Treasury Stock Retirement***

In April and May 2021, the Company retired an aggregate of 22,600,000 shares of its common stock held in treasury. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

***Issuance and Sale of Series C Convertible Preferred Stock***

In April 2021, the Company issued and sold 4,296,550 shares of its Series C Preferred Stock, at a purchase price of \$78.08578 per share, for aggregate gross proceeds of \$335.5 million. 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 (see Note 8), except that the Original Issue Price per share of the Series C Preferred Stock is \$78.08578 and the Conversion Price per share of the Series C Preferred Stock is \$15.61716. In addition, in connection with the Series C Preferred Stock financing, the definition of a qualifying initial public offering requiring the automatic conversion of all shares of outstanding preferred stock into common stock was amended to be the closing of a firm commitment public offering of common stock at a price of at least \$17.02 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization), resulting in at least \$75.0 million of gross proceeds to the Company.

Upon issuance of these shares of Series C Preferred Stock, the Company assessed the embedded conversion and liquidation features of the shares 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 as of the issuance date of the shares of Series C Preferred Stock.

***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 non-exclusive, non-sublicensable 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 obligation 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

ADAGIO THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 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.

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 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.

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.

***Stock Split***

On July 30, 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 8). 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 connection with the stock split, on July 30, 2021, the Company also increased the number of shares of common stock authorized for issuance from 19,000,000 shares to 150,000,000 shares. References to the number of shares of authorized common stock on the accompanying consolidated balance sheets have been adjusted retroactively to reflect this increase to 150,000,000 shares.

**16. Subsequent Events (Unaudited)**

***Grant of Stock Options under the 2020 Plan***

In June 2021, the Company granted options for the purchase of an aggregate of 2,025,070 shares of common stock, at an exercise price of \$12.81 per share. On July 4, 2021, the Company granted options for the purchase of

**ADAGIO THERAPEUTICS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

an aggregate of 1,861,460 shares of common stock, at an exercise price of \$12.81 per share. The aggregate grant-date fair value of the options granted under these two option grants was \$32.0 million, which is expected to be recognized as stock-based compensation expense over a weighted-average period of approximately 3.9 years.

***2021 Equity Incentive Plan***

On July 27, 2021, the Company's board of directors adopted, and on July 29, 2021 its stockholders approved, the 2021 Equity Incentive Plan (the "2021 Plan"), which will become effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's initial public offering. 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 is initially 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 remain available for issuance under the 2020 Plan, at the time the 2021 Plan becomes 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. 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.

***2021 Employee Stock Purchase Plan***

On July 27, 2021, the Company's board of directors adopted, and on July 29, 2021 its stockholders approved, the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which will become 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 initially reserved for issuance under this plan. 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.

*18,200,000 Shares*



*Common Stock*

**PROSPECTUS**

*Joint Book-Running Managers*

*MORGAN STANLEY*

*JEFFERIES*

*STIFEL*

*GUGGENHEIM SECURITIES*

*Until August 30, 2021 (25 days after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.*

*August 5, 2021*