UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

or

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

Commission File Number 001-40703

INVIVYD, INC.

(Exact name of Registrant as specified in its Charter)

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

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

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

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

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

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

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

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

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

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

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

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

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant was approximately $228.5 million based on the closing price of the registrant's common stock on June 30, 2022. The calculation excludes shares of the registrant's common stock held by current executive officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. This determination of affiliate status is not a determination for other purposes.

The number of shares of the registrant's common stock outstanding as of March 16, 2023 was 109,189,825.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission no later than 120 days after the registrant's fiscal year ended December 31, 2022, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include, but are not limited to, statements regarding our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, and are not guarantees of future performance. The words "may," "anticipate," "believe," "could," "expect," "intends," "might," "plan," "possible," "potential," "aim," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These statements speak only as of the date of this Annual Report on Form 10-K 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 our product candidates, including statements regarding the timing of our planned regulatory submissions, initiation and completion of studies or trials and related preparatory work and 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 authorization or approval of, and our ability to obtain and maintain regulatory authorizations or approvals for, our product candidates;
- our manufacturing capabilities and strategy, including the scalability and commercial viability of our manufacturing methods and processes;
- our intention to deliver new product candidates on a perpetual, ongoing basis to provide solutions for vulnerable people as new SARS-CoV-2 variants of concern ("VoCs") emerge, and the potential for us to gain alignment with regulators regarding an expedited and replicable pathway to SARS-CoV-2 monoclonal antibody ("mAb") authorization or approval;
- 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 authorized or approved for commercial use;
- our expectations regarding the scope of any approved indication for VYD222 or any other product candidate;
- our ability to successfully commercialize our product candidates, if authorized or approved;
- our ability to leverage technology and 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, if any of our product candidates are authorized or approved;
- our belief that we have sufficient cash resources to fund our operating expenses and capital expenditure requirements into the second half of 2024;
- 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 SARS-CoV-2 ("COVID-19").

The foregoing list of forward-looking statements is not exhaustive. You should refer to the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Other sections of this Annual Report on Form 10-K 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 for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report on Form 10-K will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or

revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. You should, however, review the factors and risks and other information we describe in the reports we file from time to time with the Securities and Exchange Commission (the "SEC").

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

SUMMARY OF RISK FACTORS

The following summarizes the principal factors that make an investment in us speculative or risky, all of which are more fully described in the "Risk Factors" section of this Annual Report on Form 10-K. This summary should be read in conjunction with the "Risk Factors" section and should not be relied upon as an exhaustive summary of the material risks facing our business.

Risks Related to our Financial Position and Capital Needs

- We have incurred significant losses since our inception. We expect to incur losses over the next several years and may never achieve or maintain profitability.
- We have a limited operating history and no history of commercializing products, which may make it difficult for an investor to evaluate the success of our business to date and to assess our future viability.
- We will need substantial additional funding to meet our financial obligations and to pursue our business objectives. If we are unable to raise capital when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Risks Related to the Development of our Product Candidates

- Newly emerging and future SARS-CoV-2 VoCs could reduce the activity and effectiveness of antibodies as a potential prevention of or treatment for symptomatic COVID-19, which may significantly and adversely affect our ability to complete our clinical trials, obtain authorization or approval of, and commercialize our product candidates. We may not be successful in developing our current product candidates or identifying new antibodies that are suitable either as monotherapy or as combination therapy to mitigate the risk of reduced activity against future SARS-CoV-2 VoCs.
- We intend to monitor the evolution of SARS-CoV-2 and the *in vitro* activity of adintrevimab against predominant variants in the United States ("U.S.") to identify a potential opportunity for an emergency use authorization ("EUA") request for adintrevimab in the event of a susceptible variant. However, we cannot be certain that adintrevimab or other product candidates will neutralize future variants and that we will submit an EUA for any product candidate or whether an EUA will be granted if we do submit such request.
- All of our product candidates, other than adintrevimab, are currently in clinical and preclinical development. If we are unable to successfully develop, receive regulatory approval or an 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 our product candidates represent novel approaches to the prevention and treatment of disease, there are many uncertainties regarding the development, market acceptance, third-party reimbursement coverage and commercial potential of our product candidates. We may not be successful in aligning with regulators on an expedited and replicable pathway to SARS-CoV-2 mAb authorization or approval.
- Our integrated discovery platform approach may not produce durable, broadly neutralizing, effective or safe antibodies in the timeframe necessary to address a changing virus. If we are unable to timely identify, develop, obtain authorization or approval for, and commercialize new antibodies on a perpetual, ongoing basis that keep pace with viral evolution, our business prospects will be significantly harmed.
- There can be no assurance that the public health emergency in the U.S. declared under the Public Health Service Act (the "PHS Act") and the Federal Food, Drug, and Cosmetic Act (the "FDCA") will continue to be in place for an extended period of time and that the product candidates we are developing for COVID-19 could be granted an EUA by the U.S. Food and Drug Administration (the "FDA") or similar authorization by regulatory authorities outside of the U.S. 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 candidates in the near future and instead, would need to pursue 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 authorization or approval for our product candidates, our business will be substantially harmed.
- Success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials. Our product candidates may not have favorable results in later clinical trials, if any, or receive regulatory approval.

- Lack of awareness or negative public opinion of monoclonal antibody therapies and increased regulatory scrutiny of monoclonal antibody therapies to prevent or treat COVID-19 may adversely impact the development or commercial success of our product candidates.
- We may experience delays or difficulties in the enrollment and/or retention of patients in clinical trials, or we may pause, delay or terminate enrollment in our clinical trials, which could in turn delay or prevent our receipt of necessary regulatory approvals.
- We may not be successful in our efforts to build a pipeline of additional product candidates through internal efforts or through partnerships for discovery of novel antibody product candidates.
- Our business and operations may be adversely affected by the evolving COVID-19 pandemic.

Risks Related to the Manufacturing of our Product Candidates

- Monoclonal antibody therapies are complex and difficult to manufacture, and we rely on contract manufacturers for access to capacity. We could experience manufacturing problems, may be unable to access desired manufacturing capacity within desired timeframes, or may be unable to access raw materials due to global supply chain shortages or otherwise, that result in delays in the development, supply, or commercialization of our product candidates or otherwise harm our business.
- We depend on sole-source third-party suppliers for materials that are necessary for the conduct of preclinical studies and manufacture and testing of our product candidates for clinical trials, and the loss of these third-party suppliers and manufacturers or their inability to supply us with sufficient quantities of adequate materials, or to do so at acceptable quality levels and on a timely basis, could harm our business.

Risks Related to the Commercialization of Our Product Candidates

- The affected populations for our product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.
- Our monoclonal antibody product candidates may face significant competition from vaccines, antiviral agents and other therapeutics for COVID-19 that are currently available or in development.

Risks Related to Our Intellectual Property

- If we are unable to obtain, maintain and enforce patent protection for our 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.

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

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

General Risk Factors

- We and certain of our former officers have been named as defendants in a pending securities class action lawsuit. We have also received a request from the SEC requesting certain information in connection with an investigation. This lawsuit and investigation, and potential similar or related lawsuits or investigations, could result in substantial damages, divert management’s time and attention from our business, and have a material adverse effect on our results of operations. This lawsuit and investigation, and any other lawsuits or investigations to which we are subject, will be costly to defend or comply with and are uncertain in their outcome.

PART I

Item 1. Business.

Overview

Invivyd, Inc. is a biopharmaceutical company on a mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with SARS-CoV-2. Our technology works at the intersection of evolutionary virology, predictive modeling, and antibody engineering, and is designed to identify high-quality, long-lasting antibodies with a high barrier to viral escape. We are generating a robust pipeline of product candidates which could be used in prevention or treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications.

Our vision is to provide hope for vulnerable people from viral diseases. To enable this vision, our current discovery efforts are focused on unique mAb-based product candidates that we optimize to improve breadth, potency, half-life, where applicable, and developability. Key elements that we believe differentiate our approach include: (1) cutting edge viral and epidemiological surveillance; (2) recognition of the importance of identification and availability of a repertoire of broadly neutralizing monoclonal antibodies; and (3) industry-leading B-cell mining, protein and antibody engineering as well as developability screening capabilities through our internal expertise and collaborations. We have leveraged our integrated discovery platform approach to produce candidate antibodies for the treatment and prevention of COVID-19 and lead molecules for other infectious diseases, such as influenza. In addition, we continue to evaluate therapeutic candidates for infectious diseases with high unmet medical need through in-licensing opportunities that may leverage our team's expertise and capabilities.

Globally, COVID-19 has caused millions of deaths and lasting health problems in many survivors and remains a significant global health crisis. Isolation and mental health impacts, absenteeism from work, and educational losses for children have been profound consequences of this crisis. COVID-19 persists and continues to impact patients, notably those who are immune compromised, and combating this disease will require a variety of effective and safe prevention and treatment options for years to come. By leveraging the company's capabilities, which we have developed through our experience with adintrevimab and nearly three years in the COVID-19 space, we aim to develop a continuous repertoire of SARS-CoV-2 neutralizing monoclonal antibodies to keep pace with viral evolution.

VYD222 is expected to be our second mAb candidate to enter clinical testing. We continue to plan for a Phase 1 clinical trial start in the first quarter of 2023. After a dose-ranging Phase 1 clinical trial to evaluate safety and pharmacokinetics ("PK"), we intend to initiate a clinical trial to assess the efficacy of VYD222 to prevent COVID-19, specifically in immune compromised individuals. VYD222 has demonstrated *in vitro* neutralizing activity against prior and current SARS-CoV-2 VoCs, including the Omicron sublineage XBB.1.5. VYD222 is an engineered version of adintrevimab, our investigational mAb, which demonstrated clinically meaningful results and generated a robust safety data package in global Phase 3 clinical trials for both the prevention and treatment of COVID-19 during the Delta and Omicron BA.1 waves of SARS-CoV-2 but subsequently lost *in vitro* neutralizing activity against Omicron BA.2. Utilizing our expertise in antibody engineering, we were able to restore the activity against BA.2 and other Omicron VoCs, while maintaining activity against previous VoCs. The resulting mAb, VYD222, differs from adintrevimab by only eight amino acids in the variable region.

On December 15, 2022, a joint EMA-FDA COVID-19 workshop entitled: Efficacy of monoclonal antibodies in the context of rapidly evolving SARS-CoV-2 variants was held to discuss alternative strategies for development of novel monoclonal antibody therapies, including those based on prototype products that have demonstrated safety and efficacy in clinical trials. A group of researchers, clinicians and industry representatives discussed and endorsed the use of a surrogate marker of clinical efficacy to support these alternative development strategies. As part of the joint EMA-FDA COVID-19 workshop, neutralizing antibody titers were proposed as a possible surrogate marker of protection based on data from our adintrevimab prevention clinical trial (EVADE). It is our belief that neutralizing antibody titers, combined with associated PK and safety information, may be used for a streamlined development pathway.

Since our inception, we have devoted substantially all of our resources to organizing and staffing, building an intellectual property portfolio, business planning, conducting research and development, establishing and executing arrangements with third parties for the manufacture of our product candidates, and raising capital. We rely on partnerships, external consultants and contract research organizations ("CROs") to conduct discovery, non-clinical, preclinical and clinical activities. Additionally, we rely on Contract Testing Laboratories ("CTLs") and contract development and manufacturing organizations ("CDMOs") to execute our chemistry, manufacturing and controls ("CMC") development, testing and manufacturing activities. We have engaged WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), a CDMO, for the development and manufacture of our product candidates for clinical and commercial use. Further, in 2022, we secured dedicated laboratory space and expanded our research team in order to enable internal discovery and development of our mAb candidates, while continuing to

leverage our existing partnership with Adimab. We are focused on antibody discovery and use of Adimab's platform technology, while building our internal capabilities. In addition, we engage third parties to perform ongoing research and development and other services on our behalf.

We expect to continue to rely on third parties for clinical trials and the manufacture and testing of our product candidates, as well as to perform ongoing research and development and other services on our behalf.

Our Strategy

Our goal is to discover, develop and commercialize differentiated products that could be used for the prevention and/or treatment of viral infectious diseases beginning with COVID-19. We intend to deliver new product candidates on a perpetual, ongoing basis to provide solutions for vulnerable people as new SARS-CoV-2 VoCs emerge. In order to achieve this goal, our strategy involves execution of the following key elements:

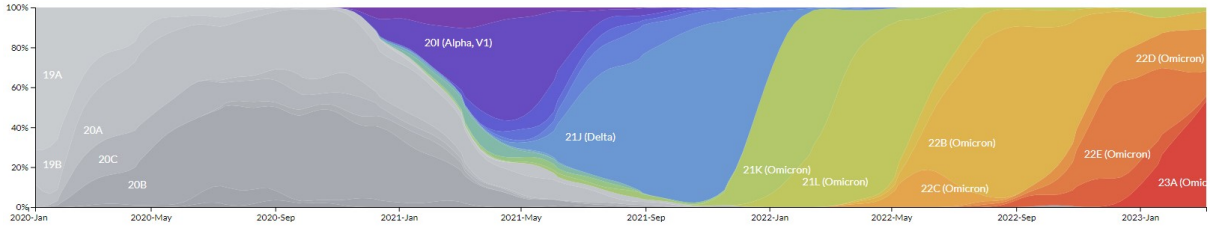
- **Obtaining regulatory authorization or approval for our lead product candidate, VYD222, for the prevention and/or treatment of COVID-19**. We continue to work with global regulators to align on an expedited and replicable pathway to SARS-CoV-2 mAb authorization or approval, with potential for authorization under an EUA or other expedited pathways. There are precedents in the influenza and COVID-19 vaccine spaces for leveraging existing safety and efficacy data to bridge quickly to new or engineered mAbs. We expect these discussions with regulators to continue as we advance the VYD222 program.
- **Successfully commercializing VYD222, if authorized or approved.** We believe the commercialization of VYD222, if authorized or approved, will involve direct sales to governments, including relevant health agencies and national health systems, and in the U.S., health insurers, integrated delivery networks and large employers. We are exploring a range of commercial go-to-market approaches in the U.S. and Europe, including building our own commercial organization, outsourcing to contract sales and marketing organizations, and/or partnering with other biopharmaceutical firms with established sales, marketing, and market access capabilities. In certain markets, such as Latin America, Asia-Pacific, including China, and Middle Eastern and African countries, we intend to commercialize VYD222 through partnerships, if authorized or approved.
- **Ensuring supply of drug product for VYD222 and future clinical product candidates.** We have partnered with WuXi Biologics for CMC development and for clinical and commercial drug substance and drug product supply of VYD222. We believe we have secured sufficient capacity for our initial supply needs, in the event that VYD222 is authorized under an EUA. We continue to evaluate access to worldwide capacity at both WuXi Biologics and other CDMOs to ensure we can meet potential future demand for VYD222. We expect to continue to use multiple CDMOs and laboratories as we advance non-clinical development activities related to our pipeline candidates.
- **Advancing differentiated product candidates to address infectious diseases through internal research, in-licensing and leveraging collaborations.** We have built a portfolio of broadly neutralizing SARS-CoV-2 antibodies as our lead disease area of focus. We have exclusive access to Adimab's industry-leading B-cell mining, protein and antibody engineering capabilities for coronavirus and influenza antibody discovery. We are currently leveraging this partnership and building internal capabilities to further expand our portfolio with additional uniquely differentiated anti-viral antibodies targeting SARS-CoV-2, as well as other infectious diseases. In addition, we have employed unique protein engineering strategies to enhance activity of our current antibodies against circulating SARS-CoV-2 VoCs. With our cutting edge viral and epidemiological surveillance, we aim to stay ahead of potential future VoCs with our repertoire of broadly neutralizing monoclonal antibodies. Finally, we continue to evaluate product candidates for infectious diseases with high unmet need through in-licensing opportunities in addition to utilizing our team's expertise and differentiated design capabilities.
- **Leveraging our team's collective expertise in development, manufacturing and commercialization to deliver future product candidates to patients.** Since our inception, we have assembled a team with deep and specific expertise in discovering, developing, manufacturing and commercializing novel treatments for infectious diseases, including extensive experience with developing mAb-based therapies. Based on our team's collective track record, including other COVID-19 product launches, we executed on the clinical, regulatory, and manufacturing plan for adintrevimab, which can be leveraged to support our next generation VYD222 program and follow-on programs.

Background on COVID-19 and SARS-CoV-2 Variants

COVID-19, the disease caused by SARS-CoV-2 and its variants, gave rise to a global pandemic in 2020. SARS-CoV-2 continues to cause infections and disease. COVID-19 remains a significant global health problem. According to estimates as of March 6, 2023 from the Johns Hopkins University, there have been approximately 676 million cases of laboratory-confirmed COVID-19 and 6.9 million COVID-19-related deaths worldwide, with approximately 104 million laboratory-confirmed cases of COVID-19 and more than 1.1 million COVID-19-related deaths in the U.S. Disease modeling conducted by several different organizations suggests that these estimates significantly underrepresent the true number of infections and deaths related to COVID-19.

Evolution of SARS-CoV-2 resulting in the rise of new variants and VoCs (see figure below) continues to pose significant issues. A VoC is a variant designated by the World Health Organization ("WHO") for which there is evidence of an increase in transmissibility, more severe disease, significant reduction in neutralization by antibodies generated during previous infection or vaccination, reduced effectiveness of treatments or vaccines, or diagnostic detection failures. From early 2022, several Omicron sublineages have represented the dominant VoCs circulating globally. Several of the amino acid substitutions within the receptor binding domain ("RBD") of the spike glycoprotein of the Omicron sublineages are associated with escape from common classes of neutralizing antibodies, thereby endowing Omicron with significantly increased resistance to serum neutralizing antibodies induced following natural infection and vaccination with ancestral strains of the virus. Importantly, all therapeutic mAbs previously authorized have had their authorizations revoked in the U.S. due to loss of activity against currently circulating VoCs. Thus, there is an urgent need to develop next-generation mAbs against current and potentially future SARS-CoV-2 VoCs.

SARS-CoV-2 Variants Continue to Emerge, Particularly Within the Omicron Sublineages



Source: nextstrain.org

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

In response to the COVID-19 pandemic, multiple therapeutics have been discovered, developed and authorized at an unprecedented speed. Currently available vaccines demonstrate limited efficacy, particularly in the immunocompromised. Monoclonal antibody therapies represent a promising alternative to active immunization.

mAbs for Prevention or Treatment of COVID-19

To date, no mAb has been approved for prevention (pre- or post-exposure) or treatment of COVID-19 in the U.S. The FDA issued an EUA for tixagevimab/cilgavimab for pre-exposure prophylaxis of COVID-19, in addition to EUAs for casirivimab/imdevimab and bamlanivimab/etesevimab for post-exposure prophylaxis of COVID-19 in certain individuals. Four monoclonal antibody products, casirivimab/imdevimab, bamlanivimab/etesevimab, sotrovimab, and bebtelovimab, have received an EUA from the FDA for the treatment of COVID-19 in patients at high risk of disease progression. Despite this progress in the availability of mAbs for the prevention and treatment of COVID-19, the clinical utility of these products has varied over time due to the emergence of SARS-CoV-2 variants demonstrating partial or full resistance to neutralization and at this time none of these products are authorized for use in prevention or treatment of COVID-19 in the U.S. due to limited to no activity against the predominant circulating Omicron sublineages. For this reason, an ongoing supply of novel or engineered mAb products are needed to protect against SARS-COV-2 variants that continue to emerge over time.

Our Approach to The Development of Antibody-based Solutions for COVID-19 and Other Viral Diseases

Our approach is designed to perpetually deliver new product candidates that keep pace with viral evolution. Our technology works at the intersection of evolutionary virology and predictive modeling, and antibody discovery and engineering. By coupling ongoing variant surveillance and prediction of viral evolution with our discovery and engineering capabilities, our

innovation engine has generated a pipeline of therapeutic candidates which could be used in prevention or treatment of serious viral diseases, starting with SARS-CoV-2. In order to provide solutions to vulnerable people as new variants emerge, we seek to leverage evolving regulatory paradigms, which may rely on surrogate endpoints, to expedite drug development. Our company has been designed to identify and develop high-quality, long-lasting antibodies with a high barrier to viral escape on a perpetual basis. Our product candidates can be tuned to improve potency, breadth of neutralization, as well as format, including half-life extending and other fragment crystallizable ("Fc") region modifications. Key elements that we believe differentiate our approach include:

- **Recognition of the importance of broadly neutralizing antibodies with a reduced risk of viral escape:** From the outset of our COVID-19 program, we chose to identify and engineer monoclonal antibodies with a high potential to resist SARS-CoV-2 variant escape. We are targeting epitopes that are (1) conserved, non-overlapping, (2) rare and under less immune pressure, and (3) potentially conserved across other human angiotensin converting enzyme-2 ("ACE-2") using sarbecoviruses (such as SARS-CoV-2), providing anticipated neutralization breadth to our monoclonal antibody candidates.
- **Continuous monitoring for SARS-CoV-2 variants:** We continuously maintain and improve our in-house monitoring system for identifying new and upcoming SARS-CoV-2 variants before they become VoCs. Further, by pinpointing dominant spike glycoprotein sites targeted by human antibody repertoires, and mapping common mutational escape routes we aim to predict future variants.
- **Industry-leading antibody mining, engineering and developability screening capabilities through internal expertise and our partnership with Adimab:** We leverage deep B-cell mining capabilities to isolate broadly neutralizing antibodies, linked to utilization of antibody engineering capabilities to improve the potency, breadth, biophysical properties and developability of our candidates we advance into preclinical development. Where applicable, we specifically engineer our antibodies, for example to extend their half-lives, modify their Fc-mediated innate immune effector functions, or alternative formats such as single-domain or bispecific molecules.
- **Expedited path to the clinic and market:** In order to deliver new mAb products that keep pace with emerging SARS-CoV-2 variants, we believe that a new, expedited approach and pathway is needed across non-clinical, clinical and CMC development to provide more rapid solutions to vulnerable people. We are leveraging and applying our experience with adintrevimab, which demonstrated clinically meaningful results and a robust safety package, to new therapeutic candidates. We seek to streamline nonclinical toxicology studies where possible, with the intention of reducing dependence on animal studies, which we believe is well in line with the FDA's position. Furthermore, the SARS-CoV-2 RBD is a well validated target and mechanism of action for monoclonal antibodies with robust safety and efficacy data generated across the class. We expect that these data will enable the application of surrogate endpoints, specifically serum neutralizing antibody titers, which can be utilized as a correlate of protection in future clinical trials. We also seek to streamline our manufacturing approach, leveraging platform processes and historical data to ensure product quality for future product candidates. We will be actively engaging with regulatory authorities to seek concurrence on these proposals as we advance our product candidates.

We are employing similar strategies for other antigenically variable viruses, such as influenza.

Commercial Opportunity

Market Opportunity

Emergency Use Authorization Environment in the U.S.

In emergency situations, such as a pandemic, and with a declaration of a public health emergency by the U.S. Secretary of the Department of Health and Human Services ("HHS"), the FDA has the authority to issue EUAs, which authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat or prevent serious or life threatening diseases or conditions. On January 31, 2020, the Secretary of HHS issued a declaration of a public health emergency related to COVID-19 under the PHS Act. On February 4, 2020, HHS determined that COVID-19 represented a public health emergency under the FDCA with significant potential to affect national security or the health and security of U.S. citizens living abroad. Subsequently, HHS declared on March 24, 2020 that circumstances existed to justify the authorization of emergency use of certain medical products, during the COVID-19 pandemic, subject to the terms of any authorization as issued by the FDA. While the Biden Administration announced that it would allow the COVID-19 public health emergency declared by HHS under the PHS Act to expire on May 11, 2023, this does not impact the FDA's ability to authorize COVID-19 drugs and biological products for emergency use. The FDA may continue to issue new EUAs going forward when criteria for issuance are met. Such ability arises from the EUA declaration and determination issued pursuant to the FDCA, which remains in effect unless or until the HHS Secretary terminates such declaration and determination, at which

point EUAs based on such declaration would cease to be in effect and the FDA may no longer issue EUAs for products covered by such declaration.

Under an EUA, products may be available via an Advance Purchase Agreement ("APA") or a traditional commercial model. In August 2022, HHS announced that Eli Lilly's bebtelovimab would be transitioning from an APA model to a traditional commercial model. Since that time, there have been no new APAs signed for any COVID mAbs. As a result, we anticipate that all future COVID-19 mAbs, including VYD222, if authorized or approved, will be distributed in the traditional commercial model. In the traditional commercial model, the manufacturer sells product directly to wholesalers and/or distributors who ship the product to various sites of care, and provider institutions and clinics can bill health plans for product. It is important to note that in an EUA a manufacturer cannot make any claims about the safety and efficacy of its drug; with a full marketing authorization biologics license applicable ("BLA"), a manufacturer can make these claims as long as they are consistent with the product's label.

Addressable Patient Populations

Pre-Exposure Prophylaxis (PrEP)

In an EUA environment, the Healthcare Provider and Patient Fact Sheets specify the patient populations eligible to receive COVID-19 treatment and prevention, and utilization of PrEP products is bound by these specifications. If we are successful with a request for EUA of VYD222 for PrEP, we estimate that the total addressable PrEP market for VYD222 in the U.S. is at least 7-8 million immunocompromised patients.

For example, the January 2023 Fact Sheet for tixagevimab/cilgavimab states, in part, that tixagevimab/cilgavimab may only be used in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

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

According to the January 2023 Fact Sheet for tixagevimab/cilgavimab, medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies;
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia);
- Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy;
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy);
- Moderate or severe primary immunodeficiency (e.g., common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, Wiskott-Aldrich syndrome);
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV); and
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, and biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents).

We have conducted several waves of market research with physicians that have reflected that there are gaps in pre-exposure prophylactic alternatives in a variety of U.S. populations. Specifically, we commissioned a consulting firm to conduct epidemiological analyses supplemented with physician interviews to quantify the size of the adult immunocompromised population in the U.S. The analysis suggested that there are potentially an additional 10-12 million adults in the U.S. with impaired immune responses attributable to conditions such as uncontrolled Type 2 diabetes and autoimmune disorders such as

severe multiple sclerosis, psoriasis, rheumatoid arthritis, and irritable bowel disease, bringing the total potential addressable immunocompromised population in the U.S. closer to 20 million patients. Extrapolated to European Union countries (whose population is approximately 1.5x that of the U.S.), there are an additional 30 million immunocompromised adults that could be candidates for PrEP therapy in the EU.

Treatment

In an EUA environment, the Healthcare Provider and Patient Fact Sheets specify the patient populations eligible to receive COVID-19 treatments. These Fact Sheets are largely driven by the COVID-19 Treatment Guidelines published by the National Institutes of Health ("NIH"), which are updated frequently.

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

Tier 1

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

Tier 2

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

Tier 3

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

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

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

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

Pediatrics

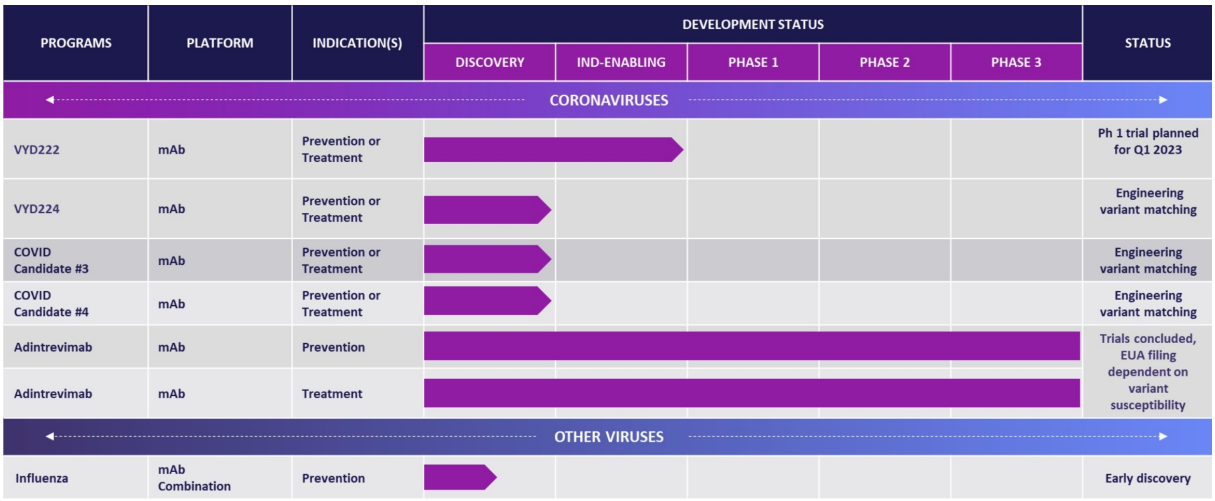
Although children are at lower risk of developing severe COVID-19 compared to adults, a subset of children experience poor outcomes, including severe acute disease, such as multisystem inflammatory syndrome ("MIS-C") and long-term sequelae of disease, also known as long COVID. Safe and effective therapies are needed to prevent severe disease and hospitalization in high-risk children as well as complications of COVID-19 such as MIS-C and long COVID. Similarly, although there is a paucity of data regarding the immune response to COVID-19 vaccines in children with moderate to severe immunocompromise, a subset of these children may have suboptimal immune responses to vaccines similar to adults with certain forms of immunocompromise and thus have the potential to benefit from a passive immune approach. Currently, the CDC recommends that children ages 6 months to 17 years receive their primary series vaccinations plus an updated (bivalent) booster. For immunocompromised children ages 5-17 years, the CDC recommends an additional primary series shot be administered for the Pfizer vaccine; for the Moderna vaccine, children ages 6 months to 17 should receive an additional primary series shot; and for the Novavax vaccine, no additional shots are currently required.

Pipeline Overview

We envision additional product development opportunities emerging from our SARS-CoV-2 discovery efforts for the prevention and/or treatment of COVID-19. We believe the discovery of additional broadly neutralizing monoclonal antibodies

that target new viral epitopes both within and outside the RBD will ensure long-lasting product activity for COVID-19 as new VoCs arise as well as for future outbreaks of disease that may emerge.

We believe that the robust antibody discovery, engineering, and development capabilities that have enabled our expedited advancement of adintrevimab may also be used to discover, engineer and develop preventative or therapeutic options for other infectious diseases, such as broadly neutralizing, half-life extended, monoclonal antibodies to provide protection against seasonal and pandemic influenza.



Manufacturing Strategy

We do not currently own or operate any manufacturing facilities and have invested significant resources to develop commercial-scale manufacturing in partnership with our contract manufacturer partner, WuXi Biologics, with whom we have been working since our inception. We have contracted with WuXi Biologics for the manufacturing of commercial-scale VYD222. VYD222 is produced using an industry standard mAb manufacturing process including a recombinant Chinese Hamster Ovary ("CHO") commercial cell line, fed-batch suspension cell culture and a chromatography column-based purification process. The drug product manufacture uses an industry standard sterile liquid drug product manufacturing process.

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

We have also established a cell line license agreement with WuXi Biologics that allows for the transfer and use in drug substance manufacturing of any cell line developed by WuXi Biologics on our behalf, including those used in the manufacture of adintrevimab, VYD222 and other clinical candidate products. This license enables cell line and manufacturing process transfer to additional contract manufacturers.

We expect to devote significant resources to the manufacture of VYD222, and we do not expect any meaningful impediments to executing our current supply plan to provide under an EUA. However, within the context of the global pandemic, sufficient capacity for commercial scale manufacturing has been constrained on a worldwide basis. We expect to have sufficient supply of VYD222 to support our clinical trial needs and to fulfill our initial supply needs upon receipt of an EUA if granted.

Our Relationship with Adimab

Since our founding in June 2020, we have focused on the development of monoclonal antibodies for both the prevention and treatment of COVID-19. Adimab is a leading provider of antibody discovery, engineering and optimization services and has established an extensive presence in the drug discovery industry.

Since July 2020, we are party to an assignment and license agreement with Adimab under which Adimab assigned to us its rights to all existing coronavirus antibodies controlled by it and their derivatives, including adintrevimab. See "—Licensing, Collaborations and Partnerships—Assignment and License Agreement with Adimab." In 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 us, we 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." In addition, in September 2022, we entered into a platform transfer agreement with Adimab. Under the platform transfer agreement, we were granted the right under certain intellectual property of Adimab to practice certain elements of Adimab's platform technology, including B-cell cloning using Adimab's proprietary yeast cell lines and other antibody optimization libraries, trade secrets, protocols and software of Adimab, to discover, engineer and optimize antibodies. We do not have access to Adimab's proprietary discovery libraries. We were also granted the right under certain intellectual property of Adimab to research, develop, make, sell and exploit such antibodies and products containing such antibodies. See "—Licensing, Collaborations and Partnerships—Platform Transfer Agreement with Adimab."

Licensing, Collaborations and Partnerships

Adimab Assignment Agreement

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

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

In July 2020, in consideration for the rights assigned and license conveyed under the Adimab Assignment Agreement, we issued 5,000,000 shares of our Series A preferred stock, then having a fair value of $40.0 million, to Adimab. In addition, under the Adimab Assignment Agreement, we are obligated to pay Adimab up to $24.6 million upon the achievement of specified development and regulatory milestones for the first two products that comprise or contain coronavirus antibodies assigned to us, antibodies discovered or optimized under the Adimab Assignment Agreement, or any derivative of such antibody (the "Products"). Through December 31, 2022, we had made aggregate milestone payments of $7.5 million to Adimab under the Adimab Assignment Agreement. We are also obligated to pay Adimab royalties of a mid single-digit percentage based on annual aggregate worldwide net sales of any Products, subject to reductions for third-party licenses, biosimilar competition, compulsory licensing and a royalty floor. The royalty term expires for each Product on a country-by-country basis beginning upon the first commercial sale of each Product and ending on the later of (i) 12 years after the first commercial sale of such Product in such country and (ii) the expiration of the last valid claim of any patent in such country that was assigned to us under the Adimab Assignment Agreement or that claims priority to any such patent. If we commercialize any Products as a diagnostic device (other than a companion diagnostic device) or as a research reagent, we must negotiate reasonable financial terms for such products.

The Adimab Assignment Agreement will expire, unless earlier terminated, on the expiration of the last-to-expire royalty term. We have the right to terminate the Adimab Assignment Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either we or Adimab may terminate the Adimab Assignment Agreement if the other party commits a material breach of the agreement and fails to cure such breach within a specified cure period after written notice is provided, except that after the initiation of the first clinical trial of a Product, Adimab may only terminate the agreement if we materially breach, and do not cure, our diligence obligation or a payment obligation. Upon expiration of the Adimab Assignment Agreement, the license becomes royalty-free, irrevocable and perpetual. Upon termination of the Adimab Assignment Agreement, all licenses and rights granted by either party will terminate and, in the case of our termination for convenience or Adimab's termination for our material breach, we are required to assign to Adimab all right, title and interest to the patents assigned by Adimab to us or that claim priority to such patents.

Through December 31, 2022, we had made aggregate payments of $10.1 million to Adimab under the Adimab Assignment Agreement, inclusive of the milestone payments.

Adimab Collaboration Agreement

In May 2021, we entered into a collaboration agreement with Adimab, as amended in November 2022 (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 (the "Evaluation Term"). We granted Adimab a non-exclusive, non-sublicensable license to certain of our patents and intellectual property solely to perform Adimab's responsibilities under the research plans. Under the agreement, we have an exclusive option on a program-by-program basis to obtain licenses and assignments to commercialize selected products containing or comprising antibodies directed against the applicable target, which option may be exercised upon the payment of a specified option fee for each program. Upon exercise of an option, Adimab will assign to us all right, title and interest in the antibodies of the optioned research program and will grant us a worldwide, royalty-free, fully paid-up, non-exclusive, sublicensable license under the Adimab platform technology to research, develop, make, use, and sell the antibodies for which we have exercised our options and products containing or comprising those antibodies.

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

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

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

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

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

Through December 31, 2022, we had made aggregate payments of $10.6 million to Adimab under the Adimab Collaboration Agreement. As of December 31, 2022, $0.3 million was due to Adimab by us.

Adimab Platform Transfer Agreement

In September 2022 (the "Effective Date"), we entered into a platform transfer agreement with Adimab (the "Adimab Platform Transfer Agreement"), under which we were granted the right under certain intellectual property of Adimab to practice certain elements of Adimab's platform technology, including B-cell cloning using Adimab's proprietary yeast cell lines and other antibody optimization libraries, trade secrets, protocols and software of Adimab, to discover, engineer and optimize antibodies. We do not have access to Adimab's proprietary discovery libraries. We were also granted the right under certain intellectual property of Adimab to research, develop, make, sell and exploit such antibodies and products containing such antibodies. The Adimab platform will be transferred to us in accordance with the terms of the Adimab Platform Transfer Agreement.

We are obligated to pay Adimab an annual fee of single digit millions on each of the first four anniversaries of the Effective Date, which will allow us to receive material improvements to the platform technology, including materially improved antibody optimization libraries, updates that provide new functionality to the platform, and software upgrades, from Adimab through June 2027. The first annual fee will become due in September 2023. Beginning in July 2027 and ending in June 2042, unless terminated earlier, we have the option to receive additional material improvements to the platform technology from Adimab, subject to a commercially reasonable fee to be negotiated by the parties.

We are also obligated to pay Adimab up to $9.5 million upon the achievement of specified development and regulatory milestones for each product under the Adimab Platform Transfer Agreement that achieves such milestones. In addition, we are obligated to pay Adimab royalties of a low single-digit percentage based on net sales of products containing an antibody discovered, engineered or optimized using Adimab's platform technology, once commercialized. The royalty rate is subject to reductions specified under the Adimab Platform Transfer Agreement. Royalties are due on a product-by-product and country-by-country basis. 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 a program antibody patent for covering the program antibody contained in such product in such country.

We may terminate the Adimab Platform Transfer Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either party may terminate the Adimab Platform Transfer Agreement in the event of a material breach by the other party that is not cured within specified periods or in connection with the other party's insolvency.

Through December 31, 2022, we had made aggregate payments of $3.0 million to Adimab under the Adimab Platform Transfer Agreement.

Population Health Partners, L.P.

In November 2022 (the "PHP Effective Date"), we entered into a Master Services Agreement with Population Health Partners, L.P. ("PHP"), pursuant to which PHP agreed to provide services and create deliverables for us as agreed between us and PHP and set forth in one or more work orders under such agreement (the "PHP MSA"). The term of the PHP MSA commenced on the PHP Effective Date and will continue for a period of one year, unless terminated earlier in accordance with its terms. On the PHP Effective Date, we and PHP entered into the first work order under the PHP MSA (the "PHP Work Order"), pursuant to which PHP agreed to advise and counsel us regarding clinical development and regulatory matters with respect to our product candidates. The PHP Work Order is effective for six months from the PHP Effective Date and may be extended by written agreement of us and PHP. The PHP MSA contains customary confidentiality provisions and representations and warranties of the parties, as well as mutual non-solicitation of certain employees during the term of the PHP MSA and for a period of one year thereafter. Clive Meanwell, M.D. and Tamsin Berry, members of our board of directors, are Managing Partner and Partner of PHP, respectively.

As compensation for the services and deliverables under the PHP Work Order, we are obligated to pay PHP a cash fee of $500,000 per month during the term of the PHP Work Order for an aggregate fee of $3,000,000 (the "Aggregate Fee"). In the event that (i) we terminate the PHP Work Order for any reason other than material breach by PHP or (ii) PHP terminates the PHP Work Order due to material breach by us, in each case, pursuant to the terms of the PHP MSA, then we would be required to pay PHP the balance of the Aggregate Fee as of the date the PHP Work Order is terminated. The cash fee is subject to change if the parties extend the term of the PHP Work Order in accordance with the terms thereof.

In addition to the cash compensation, on the PHP Effective Date, we issued a warrant to purchase shares of our common stock, par value $0.0001 ("Common Stock"), to PHP (the "PHP Warrant"). The exercise price of the PHP Warrant is $3.48 per share of Common Stock, which is equal to the Nasdaq Official Closing Price of a share of Common Stock on the trading day

immediately prior to the PHP Effective Date. The PHP Warrant is exercisable for up to an aggregate of 6,824,712 shares of Common Stock, and vests in up to three separate tranches upon certain milestones. See Note 8 to our annual consolidated financial statements appearing at the end of this Annual Report on Form 10-K for further details.

As of December 31, 2022, $0.8 million was due to PHP by us under the PHP Work Order.

Research Collaboration and License Agreement with The Scripps Research Institute

In August 2021, we entered into a research collaboration and license agreement (the "Research Agreement") with The Scripps Research Institute ("TSRI"). Under the terms of the Research Agreement, TSRI performed research activities to identify vaccine candidates for the prevention, diagnosis or treatment of influenza or beta coronaviruses (the "Research Program").

In April 2022, we provided written notice to TSRI to terminate the Research Agreement. Following early termination in the second quarter of 2022, all licenses were terminated and reverted to TSRI.

Through December 31, 2022, we had made aggregate payments of $4.0 million to TSRI under the Research Agreement.

Cell Line License Agreement with WuXi Biologics

We are also party to a Cell Line License Agreement with WuXi Biologics, entered into as of December 2, 2020, as amended on February 2, 2023. 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 Biologics Limited ("Biocon") to combat the ongoing COVID-19 crisis in southern Asia. Under the license agreement, we granted Biocon exclusive rights to manufacture and commercialize an antibody treatment in India and additional select emerging markets based on the commercial process developed for adintrevimab. As part of the agreement, Biocon will be granted access to the data from our Phase 2/3 adintrevimab clinical trials and access to our EUA package, if applicable, including 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 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 active COVID-19 antibody-based programs include AstraZeneca plc, Eli Lilly and Co, Regeneron Pharmaceuticals, Inc. in collaboration with Roche Pharmaceuticals, Vir Biotechnology, Inc., and Aerium Therapeutics. In addition, companies that have approved or authorized antiviral programs for the treatment of COVID-19 include Merck and Co., Inc. (oral), Pfizer Pharmaceuticals (oral), and Gilead (IV). Beyond antibody and small molecule antiviral treatments, we also face competition from SARS-CoV-2 vaccines that are either available under an 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 previously obtained EUAs from the FDA for the treatment of mild to moderate COVID-19 in high risk patients and the prevention of

COVID-19 in immunocompromised patients, and others in the future may obtain FDA or other regulatory approval or authorization more rapidly than we may, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price and the availability of reimbursement from government and other third-party payors.

Intellectual Property

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

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

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

VYD222, Adintrevimab, and Other Antibodies

As of March 16, 2023, we own one patent family for which we have three issued U.S. patents (U.S. 11,192,940, issued December 7, 2021; U.S. 11,220,536, issued January 11, 2022; and U.S. 11,414,479, issued August 16, 2022), one pending U.S. non-provisional patent application, and foreign patent applications in Argentina, Brazil, Canada, China, Europe, India, Japan, Mexico, Singapore, South Africa, Taiwan, and Thailand. This patent family is directed to broadly neutralizing anti-coronavirus antibodies, including ADG20 (adintrevimab) and ADG10, and uses thereof. These patents and patent applications and any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon such applications, if issued, are expected to expire in 2041, without taking into account any possible patent term adjustment or extension.

As of March 16, 2023, we own a second patent family for which we have filed one PCT patent application. This patent family is directed to formulations and methods of use for ADG20 (adintrevimab). Any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon such application, if issued, are expected to expire in 2042, without taking into account any possible patent term adjustment or extension.

As of March 16, 2023, we own a third patent family for which we have filed one PCT patent application and one foreign application in Taiwan. This patent family is directed to formulations and methods of use for ADG20 (adintrevimab). Any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon such applications, if issued, are expected to expire in 2042, without taking into account any possible patent term adjustment or extension.

As of March 16, 2023, we own a fourth patent family for which we have filed one PCT patent application and two foreign patent applications in Argentina and Taiwan. This patent family is directed to additional broadly neutralizing anti-coronavirus

antibodies, combination therapies, and uses thereof. These patent applications and any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon such applications, if issued, are expected to expire in 2042, without taking into account any possible patent term adjustment or extension.

As of March 16, 2023, we own two additional patent families for which we have filed provisional U.S. patent applications. The first patent family is directed to additional broadly neutralizing anti-coronavirus antibodies, combination therapies, and uses thereof, and includes four U.S. provisional patent applications. The second patent family is directed to additional broadly neutralizing anti-coronavirus antibodies, including VYD222, as well as 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 2043, without taking into account any possible patent term adjustment or extension.

Trade Secrets and Proprietary Information

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

Government Regulation

In the U.S., we are subject to extensive regulation by the FDA and other federal, state, and local regulatory agencies. In the U.S., biologics such as our product candidates are licensed by the FDA for marketing under the PHS Act and regulated under the FDCA. Both the FDCA and the PHS Act and their corresponding regulations govern, among other things, the testing, development, manufacturing, quality control, safety, purity, potency, efficacy, approval, labeling, packaging, storage, record keeping, distribution, marketing, sales, import, export, reporting, advertising and other promotional practices involving biologics. FDA clearance must be obtained before clinical testing of biologics product candidates. FDA licensure also must be obtained before biologics can be marketed. Additionally, significant regulatory aspects in the European Union are addressed in a centralized way through the European Medicines Agency (the "EMA"), and the European Commission, however country-specific regulation remains essential in many respects. Further, any failure to comply with applicable laws and regulations could have a material negative impact on our ability to successfully develop and commercialize product candidates, and therefore on our financial performance. In addition, the laws, rules and regulations that apply to our business are subject to change and it is difficult to foresee whether, how, or when such changes may affect our business. 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 candidate may be marketed in the U.S. generally involves the following:

- completion of nonclinical laboratory tests and animal studies according to current Good Laboratory Practices ("cGLP") and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- preparation of clinical trial material in accordance with applicable current ("cGMP");
- submission to the FDA of an application for an Investigational New Drug Application ("IND"), which contains, among other data and information, pre-clinical testing results and provides a basis for the FDA to conclude that there is an adequate basis for testing the drug in humans. If the FDA does not object to the IND application within 30 days of submission, the clinical testing proposed in the IND may begin. Even after the IND has gone into effect and clinical testing has begun, the FDA may put the clinical trials on "clinical hold," suspending (or in some cases, ending) them because of safety concerns or for other reasons;

- approval by an institutional review board ("IRB"), reviewing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials according to the FDA's bioresearch monitoring regulations and current Good Clinical Practices ("cGCP"), which establish standards for conducting, recording data from, and reporting the results of clinical trials, with the goals of assuring that the data and results are credible and accurate and that study participants' rights, safety and well-being are protected, 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 candidate for its intended use. Each clinical trial must be conducted under a protocol which details, among other things, the study objectives and parameters for monitoring safety and the efficacy criteria, if any, to be evaluated. The protocol is submitted to the FDA as part of the IND and reviewed by the agency;
- 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 a potential FDA pre-licensure inspection prior to BLA approval of the manufacturing facility or facilities where the biologic product candidate is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the biologic product candidate'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; and
- FDA review and approval, or licensure, of the BLA and payment of associated user fees, when applicable.

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 cGLP and the Animal Welfare Act, which are enforced by the Department of Agriculture.

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 before clinical testing may begin. 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 raises concerns or questions regarding the proposed clinical trials, including whether subjects will be exposed to unreasonable health risks, 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 cGCP requirements, including the requirement that all research subjects or their 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.

A sponsor who wishes to conduct a clinical trial outside the U.S. may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. Foreign studies conducted under an IND must meet the same requirements that apply to studies being conducted in the U.S. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of a new drug application ("NDA") so long as the clinical trial is conducted in compliance with cGCP, including review and approval by an independent ethics committee and compliance with informed consent principles, and the FDA is able to validate the data from the study through an on-site inspection if deemed necessary.

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

- ***Phase 1***. The biologic product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some biologic product candidates for rare diseases, the initial human testing is often conducted in patients. In addition to testing for safety, the purpose of these clinical trials is to assess the metabolism, pharmacologic action, and side effect tolerability of the biologic product candidate.
- ***Phase 2***. The biologic product candidate is evaluated in a limited population of patients afflicted with the target disease to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the biologic product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- ***Phase 3***. The biologic product candidate is further evaluated in terms of dosage, clinical efficacy, potency and safety in an expanded patient population (typically from several hundred to several thousand subjects) at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the biologic product candidate and provide an adequate basis for product labeling. In biologics for rare diseases where patient populations are small and there is an urgent need for treatment, Phase 3 trials might not be required if an adequate risk/benefit can be demonstrated from the Phase 2 trial.

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

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 cGMP 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 National Institutes of Health for public dissemination on its clinicaltrials.gov website. Sponsors or distributors of investigational products for the diagnosis, monitoring or treatment of one or more serious diseases or conditions must also have a publicly available policy on evaluating and responding to requests for expanded access requests.

U.S. Review and Approval Processes

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

Under the Prescription Drug User Fee Act, as amended (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 performance goals generally provide for action on a BLA within 10 months after the 60-day filing date, or within 12 months of the BLA submission. That deadline can be extended under certain circumstances, including by the FDA's requests for additional information. The targeted action date can also be shortened to within 6 months after the 60-day filing date, or 8 months after BLA submission, for product candidates that are granted priority review designation because they are intended to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. 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 cGMP 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 Risk Evaluation and Mitigation Strategy ("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 candidate is manufactured. The FDA will not approve the product candidate unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are 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 cGCP requirements. To assure cGMP and cGCP compliance, an applicant must incur a significant expenditure of time, money and effort in the areas of training, record keeping, production and quality control, among others.

After the FDA evaluates a BLA, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the product candidate with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the BLA identified by the FDA. The Complete Response Letter may require additional clinical data and/or one or more additional pivotal Phase 3 clinical trials, and/or other significant and time-consuming requirements related to clinical trials, non-clinical studies or manufacturing. 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. The applicant may also appeal the decision through the FDA's formal dispute resolution process. Even if such additional data and information are submitted in a BLA resubmission, the FDA may ultimately decide that the BLA does not satisfy the criteria for 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 a product candidate 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 REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, sometimes referred to as Phase 4

clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized. As a condition for approval, the FDA may also require additional nonclinical testing as a Phase 4 commitment. Product approvals may be withdrawn for non-compliance with regulatory requirements if problems occur following launch, or if the FDA determines that the product is no longer safe or effective.

Pediatric Trials

The Food and Drug Administration Safety and Innovation Act, which was signed into law on July 9, 2012, amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan ("PSP") within sixty days of an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from non-clinical studies, early phase clinical trials, and/or other clinical development programs. The FDA, if it learns of new information, may also request that the sponsor amend the initial PSP.

Emergency Use Authorization in the U.S.

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

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

The FDA expects EUA holders to work toward submission of full applications, such as an NDA, as soon as possible. An EUA is also subject to additional conditions and restrictions and is product-specific. Once granted, an EUA will remain in effect and generally terminate on the earlier of (1) the determination by the Secretary of HHS that the public health emergency has ceased or (2) a change in the approval status of the product such that the authorized use(s) of the product are no longer unapproved. After the EUA is no longer valid, the product is no longer considered to be legally marketed and one of the FDA's non-emergency premarket pathways would be necessary to resume or continue distribution of the subject product.

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

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

FDA has issued numerous guidance to sponsors seeking to obtain EUAs to diagnose and treat COVID-19. While the Biden Administration announced that it would allow the COVID-19 public health emergency declared by HHS under the PHS Act to expire on May 11, 2023, this does not impact the FDA's ability to authorize COVID-19 drugs and biological products for emergency use. The FDA may continue to issue new EUAs going forward when criteria for issuance are met. Such ability arises from the EUA declaration and determination issued pursuant to the FDCA, which remains in effect unless or until the HHS Secretary terminates such declaration and determination, at which point EUAs based on such declaration would cease to be in effect and the FDA may no longer issue EUAs for products covered by such declaration.

Post-Approval Requirements

Maintaining 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 cGMP. If ongoing regulatory requirements are not met, safety problems occur after a product reaches market, or additional data change the FDA's view of the efficacy of the product, the FDA may take actions to change the conditions under which the product is marketed, such as requiring labeling modifications, restricting distribution, or even withdrawing approval. We 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 product candidates are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation.

Good Manufacturing Practices. Companies engaged in manufacturing drug products or their components must comply with applicable cGMP requirements, which include requirements regarding organization and training of personnel, facility registration, building and facilities, equipment, control of components and drug product containers, closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls and records and reports. The FDA inspects equipment, facilities and manufacturing processes before approval and conducts periodic re-inspections after approval. If, after receiving approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the NDA), additional regulatory review and approval may be required. Failure to comply with applicable cGMP requirements or the conditions of the product's approval may lead the FDA to take enforcement actions, such as issuing a warning letter, or to seek sanctions, including fines, civil penalties, injunctions, suspension of manufacturing operations, imposition of operating restrictions, withdrawal of FDA approval, seizure or recall of products, and criminal prosecution. Although we periodically monitor FDA compliance of the third parties on which we rely for manufacturing our product candidates, we cannot be certain that our present or future third-party manufacturers will consistently comply with cGMP or other applicable FDA regulatory 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.

Sales and Marketing. We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, promotion to healthcare practitioners, 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. In addition to FDA restrictions on marketing of pharmaceutical products, state and federal fraud and abuse laws have been applied to restrict certain marketing practices in the pharmaceutical industry. Discovery of previously unknown problems or the failure to comply with applicable regulatory requirements, including the FDA, the Department of Justice, the Office of the Inspector General of the Department of Health and Human Services, and/or state authorities may result in restrictions on the marketing of a product or withdrawal of the product from the market, as well as possible civil or criminal sanctions. Failure to comply with applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval or license revocation, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits or civil or criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on our business and operations.

Other Requirements. Companies that manufacture or distribute drug products pursuant to approved NDAs must meet numerous other regulatory requirements, including adverse event reporting, submission of periodic reports, and record-keeping obligations.

We are also subject to federal, state and foreign laws and regulations governing data privacy and security of health information, and the collection, use and disclosure, and protection of health-related and other personal information. 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 that may affect our business, including recently enacted laws in all jurisdictions where we operate. Numerous federal and state laws, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection and privacy laws, (including, for example, Section 5 of the Federal Trade Commission Act of 1914 ("FTC Act"), and the California Consumer Privacy Act ("CCPA"), as amended by the California Privacy Rights Act ("CPRA")) govern the collection, use and disclosure of personal information. These laws may differ from each other in significant ways, thus complicating compliance efforts. Federal regulators, state attorneys general, and plaintiffs' attorneys have been and will likely continue to be active in this space. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The European Union's General Data Protection Regulation ("GDPR") and other data protection, privacy and similar national, state/provincial and local laws may restrict the access, use and disclosure of patient health information abroad. Compliance efforts will likely be an increasing and substantial cost in the future.

Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant penalties), private litigation and/or adverse publicity that could negatively affect our business. 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 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder. HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their "business associates" – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. Depending on the facts and circumstances, we could be subject to significant penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Also at the federal level, the Federal Trade Commission ("FTC"), sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individuals about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations for failing to honor the privacy promises made to individuals about how the company handles consumers' personal information; such failure may also constitute unfair or deceptive acts or practices in violation of the FTC Act. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

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 the process for the development and FDA review of certain biological product candidates that are intended for the treatment of serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs. 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 more frequent 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 from the 60-day filing date rather than the standard goal of 10 months from the 60-day filing date 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 accelerated approval, the FDA may require a sponsor of a biological product receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoints, and the biological product may be subject to accelerated withdrawal procedures.

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

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

Biologics Price Competition and Innovation Act

The Biologics Price Competition and Innovation Act of 2009 ("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 (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 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 standalone 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 (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 U.S. Patent and Trademark Office (the "USPTO"), in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Regulation Outside of the U.S.

In addition to regulations in the U.S., 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 product candidates. 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 U.S. 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 ("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 cGCP 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 as the Clinical Trials Regulation (Regulation (EU) No 536/2014) came into application on January 31, 2022. The Clinical Trial Regulation is directly applicable in all the European Union Member States, repealing the current Clinical Trials Directive (Directive 2001/20/EC). The new Clinical Trials Regulation allows sponsors to begin and conduct a clinical trial in accordance with the Clinical Trials Directive during a transitional period of one year after the January 31, 2022 application date. The transition period for clinical trials ongoing at the moment of applicability will be a maximum of three years after the date of application of the Clinical Trials Regulation. Clinical trials authorized under the current Clinical Trials Directive before January 31, 2023 can continue to be conducted under the Clinical Trials Directive until January 31, 2025. An application to transition ongoing trials from the current Clinical Trials Directive to the new Clinical Trials Regulation must be submitted and authorized in time before the end of the transitional period. The Clinical Trials 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. The main characteristics of the Clinical Trials Regulation include: (i) a streamlined application procedure through a single entry point; (ii) a single set of documents to be prepared and submitted for an application as well as simplified reporting procedures for clinical trial sponsors; and (iii) a harmonized procedure for the assessment of applications for clinical trials.

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a Marketing Authorization Application ("MAA"). The application used to file the BLA in the U.S. is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. In the European Union, marketing authorization for a medicinal product can be obtained through a centralized procedure, mutual recognition procedure, decentralized procedure, or the national procedure of an individual European Union Member State. A marketing authorization, irrespective of its route to authorization, may be granted only to an applicant established in the European Union.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all 27 European Union Member States and three of the four European Free Trade Association States (Iceland, Liechtenstein and Norway). Under the centralized procedure, the Committee for Medicinal Products for Human Use (the "CHMP") established at the EMA is responsible for conducting the initial assessment of a product. The maximum timeframe for the evaluation of an MAA is 210 days. This period excludes clock stops during which additional information or written or oral explanation is to be provided by the applicant in response to questions posed by the CHMP. Accelerated evaluation might be granted by the CHMP in exceptional cases, such as when a medicinal product is expected to be of a major public health interest. A major public health interest defined by three cumulative criteria: (i) the seriousness of the disease (for example, heavy disabling or life-threatening diseases) to be treated; (ii) the absence or insufficiency of an appropriate alternative therapeutic approach; and (iii) the anticipation of high therapeutic benefit. If the CHMP accepts to review a medicinal product as a major public health interest, the time limit of 210 days will be reduced to 150 days. It is, however, possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Irrespective of the related procedure, at the completion of the review period the CHMP will provide a scientific opinion concerning whether or not a marketing authorization should be granted in relation to a medicinal product. This opinion is based on a review of the quality, safety, and efficacy of the product. Within 15 days of the adoption, the EMA will forward its opinion to the European Commission for its decision. Following the opinion of the EMA, the European Commission makes a final decision to grant a centralized marketing authorization. The centralized procedure is mandatory for certain types of medicinal products, including orphan medicinal products, medicinal products derived from certain biotechnological processes, advanced therapy medicinal products and medicinal products containing a new active substance for the treatment of certain diseases. This

route is optional for certain other products, including medicinal products that are of significant therapeutic, scientific or technical innovation, or whose authorization would be in the interest of public or animal health at European Union level.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate approval by, the authorities of each European Union Member State in which the product is to be marketed. This application process is identical to the application that would be submitted to the EMA for authorization through the centralized procedure and must be completed within 210 days, excluding potential clock-stops, during which the applicant can respond to questions. The relevant European Union Member State prepares a draft assessment and drafts of the related materials. The relevant European Union Member States must decide whether to approve the assessment report and related materials. If a European Union Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all European Union Member States.

The mutual recognition procedure is similarly based on the acceptance by the relevant authorities of the European Union Member States of the marketing authorization of a medicinal product by the relevant authorities of other European Union Member States. The holder of a national marketing authorization may submit an application to the authority of a European Union Member State requesting that this authority recognize the marketing authorization delivered by the authority of another European Union Member State.

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 scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. 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 active substances 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. The overall ten-year period will be extended to a maximum of 11 years if, during the first eight years of those 10 years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new active substance, and products may not qualify for data exclusivity.

A Pediatric Investigation Plan ("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. For treatments and vaccines for COVID-19, the EMA reviews applications in an expedited manner for agreement of a PIP, deferrals or waivers and accelerates compliance checks, to speed up these products' development and approval. Several rewards and incentives for the development of pediatric medicines for children are available in the European Union. Medicines authorized with the results of studies from a PIP included in the product information are eligible for an extension of their supplementary protection certificate by six months, even when the results of the studies are negative. Scientific advice and protocol assistance at the EMA are free of charge for questions relating to the development of pediatric medicines. Medicines developed specifically for children that are already authorized but are not protected by a patent or supplementary protection certificate are eligible for a pediatric-use marketing authorization, which if granted, provides 10 years of market protection.

The Medicines and Healthcare products Regulatory Agency ("MHRA") is responsible for regulating the United Kingdom medicinal products market (Great Britain and Northern Ireland). The United Kingdom left the European Union on January 31, 2020, following which existing European Union 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 European Union 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 ("TCA") that became effective on January 1, 2021.

Among the changes that have had a direct impact are that Great Britain (England, Scotland and Wales) is now treated as a "third country," a country that is not a member of the European Union and whose citizens do not enjoy the European Union right to free movement. As a result of the Northern Ireland Protocol, different rules apply in Northern Ireland than in Great Britain. In general, Northern Ireland continues to follow the European Union regulatory regime, but its national medicines and medical devices authority remains the MHRA. Following the effectiveness of the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019 on January 31, 2020, the United Kingdom regulatory regime for clinical trials, marketing authorizations, importing, exporting and pharmacovigilance largely mirrors that of the European Union. As part of the TCA, the European Union and the United Kingdom will recognize cGMP inspections carried out by the other party and the acceptance of official cGMP documents issued by the other party. The TCA also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The United Kingdom has unilaterally agreed to accept European Union batch testing and batch release, and any change to this position is subject to a minimum two year notice period. However, the European Union continues to apply European Union laws that require batch testing and batch release to take place in the European Union territory. This means that medicinal products that are tested and released in the United Kingdom must be retested and re-released when entering the European Union market for commercial use. As it relates to marketing authorizations, Great Britain has introduced a separate regulatory submission process, approval process and a separate national marketing authorization. However, Great Britain has a "European Commission Decision Reliance Procedure" which provides for an expedited authorization procedure for products that have received a positive opinion in the European Union. This centralized procedure under the MHRA aims to issue a Great Britain marketing authorization on or shortly after a European Union marketing authorization if it receives the application within 5 days of the positive opinion. The European Commission Decision Reliance Procedure is currently in place until December 31, 2023 and the MHRA has publicly stated that the procedure will be replaced by a broader international recognition procedure beyond this. Northern Ireland, however, continues to be covered by the marketing authorizations granted by the European Commission. Under the Windsor Framework announced by the United Kingdom government on February 27, 2023 but which is still pending formal United Kingdom and European Union approvals, future marketing authorizations granted by the European Commission would not have effect in Northern Ireland and instead Northern Ireland would be subject to the same MHRA authorization procedures as Great Britain.

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 cGCP 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 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 U.S. 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 product candidates 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 ("CMS"), an agency within HHS. CMS decides whether and to what extent products will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree.

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

products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary, appropriate for the specific patient, cost-effective, supported by peer-reviewed medical journals, included in clinical practice guidelines, and neither cosmetic, experimental nor investigational. Further, increasing efforts by third-party payors in the U.S. 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 to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain FDA or comparable regulatory approvals. 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. 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. In the European Union, each European Union Member State can restrict the range of medicinal products for which its national health insurance system provides reimbursement and can control the prices of medicinal products for human use marketed on its territory. As a result, following receipt of marketing authorization in a European Union Member State, through any application route, the applicant is required to engage in pricing discussions and negotiations with the relevant pricing authority in the individual European Union Member State. The governments of the European Union Member States influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some European Union Member States operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed upon. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other European Union Member States allow companies to fix their own prices for medicinal products, but monitor and control company profits. Others adopt a system of reference pricing, basing the price or reimbursement level in their territories either on the pricing and reimbursement levels in other countries or on the pricing and reimbursement levels of medicinal products intended for the same therapeutic indication. Further, some European Union Member States approve a specific price for the medicinal product or may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal on the market. The downward pressure on healthcare costs in general, particularly prescription drugs, has become more intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, we may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some European Union Member States. These European Union Member States include France, Germany, Ireland, Italy and Sweden. HTA is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. HTA generally focuses on the clinical efficacy and effectiveness, safety, cost, and cost-effectiveness of individual medicinal products as well as their potential implications for the healthcare system. Those elements of medicinal products are compared with other treatment options available on the market. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual European Union Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product varies between European Union Member States.

In addition, pursuant to Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, a voluntary network of national authorities or bodies responsible for HTA in the individual European Union Member States was established. The purpose of the network is to facilitate and support the exchange of scientific information concerning HTAs. This may lead to harmonization of the criteria taken into account in the conduct of HTAs between European Union Member States and in pricing and reimbursement decisions and may negatively affect price in at least some European Union Member States.

On January 31, 2018, the European Commission adopted a proposal for an HTA Regulation intended to set out a European Union-wide framework for HTA and boost cooperation among European Union Member States in assessing health technologies, including new medicinal products. The HTA Regulation provides the basis for permanent and sustainable cooperation at the European Union level for joint clinical assessments in these areas and is therefore complementary to

Directive 2011/24/EU. The HTA Regulation was adopted on December 13, 2021, and entered into force on January 11, 2022. The HTA Regulation will apply to all European Union Member States beginning on January 12, 2025. The HTA Regulation provides that European Union Member States will be able to use common HTA tools, methodologies, and procedures across the European Union. Individual European Union Member States will continue to be responsible for drawing conclusions on the overall value of new health technology for their healthcare system, and pricing and reimbursement decisions.

Healthcare Laws and Regulations

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

- The federal Anti-Kickback Statute makes it illegal for any person or entity to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is in exchange for or to induce the referral of business, including the purchase, order, lease, or arranging for or recommending purchasing, leasing, or ordering 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. Analogous anti-kickback laws and regulations exist in the European Union;
- 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, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit money to the federal government, or knowingly concealing or improperly avoiding or decreasing an obligation to pay money to the federal government. In the European Union, the advertising and promotion of products are subject to laws governing promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), as approved by the competent authorities in connection with a marketing authorization approval. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the European Union. Other applicable laws at the European Union level and in the individual European Union Member States also apply to the advertising and promotion of medicinal products, including laws that prohibit the direct-to-consumer advertising of prescription-only medicinal products and further limit or restrict the advertising and promotion of products to the general public and to health care professionals. Violations of the rules governing the promotion of medicinal products in the European Union could be penalized by administrative measures, fines and imprisonment;
- 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 its 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. In the European Union, there has been increased attention to privacy and data security issues that could potentially affect our business, including the GDPR, which became effective on May 25, 2018. The GDPR regulates the processing of personal data and imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data from the European Union to the U.S., including health data from clinical trials. The GDPR 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. Failure to comply with the requirements of GDPR may result in fines of up to 20,000,000 Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties;

- 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, ownership interests, or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals. In the European Union, interactions between pharmaceutical companies and physicians are also governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products, which is prohibited in the European Union, is governed by the national anti-bribery laws of the European Union Member States, as described below. Violation of these laws could result in substantial fines and imprisonment. Certain European Union Member States, or industry codes of conduct, require that payments made to physicians be publicly disclosed. Moreover, agreements with physicians must often be the subject of prior notification and approval by the physician's employer, his/her competent professional organization, and/or the competent authorities of the individual European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment; and
- The Foreign Corrupt Practices Act ("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. Our business activities outside of the U.S. are subject to similar anti-bribery or anti-corruption laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct or rules of other countries in which we operate, including the UK Bribery Act of 2010.

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 U.S. and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system. The U.S. government, state legislatures and foreign governments also have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for branded prescription drugs 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 laws and 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 Medicare reimbursement may result in a similar reduction in payments from private payors.

The ACA substantially changed the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. The ACA is intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on pharmaceutical and medical device manufacturers and impose additional health policy reforms. Among other things, the ACA expanded manufacturers' rebate

liability under the Medicaid Drug Rebate Program by increasing the minimum Medicaid rebate for both branded and generic drugs and biologics, expanded the 340B program, and revised the definition of average manufacturer price ("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. Additional regulations governing this program have been finalized since that date. Since enactment, there have been significant efforts to modify or challenge the ACA. For example, the Tax Cuts and Jobs Act (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, commonly referred to as the individual mandate.

Other legislative changes have been proposed and adopted since passage of the ACA. For example, on August 2, 2011, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction, which triggered the legislation's automatic reductions. In concert with subsequent legislation, this has resulted in aggregate reductions to Medicare payments to providers of, on average, 2% per fiscal year. Sequestration is currently set at 2% and will increase to 2.25% for the first half of fiscal year 2030, to 3% for the second half of fiscal year 2030, and to 4% for the remainder of the sequestration period that lasts through the first six months of fiscal year 2031.

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 AMP, for single-source and innovator multiple-source drugs, beginning January 1, 2024. Additionally, on January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

On August 16, 2022, President Biden signed into law the Inflation Reduction Act of 2022 ("IRA"), which, among other things, establishes a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the average sales price of a Part B drug increases faster than the pace of inflation. Failure to timely pay a Part B inflation rebate is subject to a civil monetary penalty. The IRA also establishes a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers will owe rebates if the AMP of a Part D drug increases faster than the pace of inflation. The IRA also creates a drug price negotiation program under which the prices for Medicare units of certain high Medicare spend drugs and biologics without generic or biosimilar competition will be capped by reference to, among other things, a specified non-federal AMP, starting in 2026. Failure to comply with requirements under the drug price negotiation program is subject to an excise tax and/or a civil monetary penalty. The IRA further makes several changes to the Medicare Part D benefit, including a limit on annual out-of-pocket costs, and a change in manufacturer liability under the program that could negatively affect the profitability of our product candidates. Congress continues to examine various policy proposals that may result in pressure on the prices of prescription drugs in the government health benefit programs. The IRA or other legislative change could impact the market conditions for our product candidates. 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.

Further legislative and regulatory changes related to the aforementioned laws remain possible. 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 its implementing regulations, changes to the Medicare and Medicaid programs, changes regarding the federal government's authority to directly negotiate drug prices and changes stemming from other healthcare reform measures, especially with regard to healthcare access or financing or other legislation in individual states, could have a material adverse effect on the healthcare industry 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, among other things, amended the ACA, effective January 1, 2019, to close the coverage gap in most Medicare drug plans by increasing from 50%to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. The IRA subsequently replaces the Part D coverage cap discount program with a new Part D discounting program beginning in 2025.

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, best price, and Medicaid drug rebate data, revisions to the Medicaid rebate formula, best price, and AMP definition could cause the required 340B discounts to increase.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Such scrutiny has resulted in several recent congressional inquiries, executive orders and proposed and enacted federal and state legislation and regulation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this rule has been delayed until January 1, 2027.

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 governmental health benefit programs or commercial payors will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. Further, it is possible that additional governmental action is taken in response to the COVID-19 pandemic.

Employees and Human Capital Resources

As of February 1, 2023, we had 84 full-time employees and two part-time employees. Of our 86 full- and part-time employees, approximately 23 have Ph.D. or M.D. degrees and 58 are engaged in research and development activities. We have a remote workforce, with approximately 37% of our employees based in Massachusetts, 12% based in California, 9% based in Florida, 7% based in New Jersey, 5% based in North Carolina, 5% based in Pennsylvania, and the remaining 25% in various additional states. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be strong.

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

Facilities

Since our inception, we have been a virtual company with our employees working remotely from their homes. We rent office space in an office building in Waltham, Massachusetts for general and administrative purposes. We rent laboratory and office space in a shared laboratory building in Newton, Massachusetts for research and development purposes. We believe that our remote working approach is adequate to meet our ongoing needs, and that, if we require physical facilities, we will be able to obtain additional facilities on commercially reasonable terms.

Item 1A. Risk Factors.

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

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 $241.3 million and $226.8 million for the years ended December 31, 2022 and 2021, respectively. As of December 31, 2022, we had an accumulated deficit of $533.4 million. Since our inception, we have financed our operations with net proceeds of $464.7 million raised in our private placements of preferred stock, including the sale of our Series C preferred stock in April 2021, and approximately $327.5 million of net proceeds (after deducting underwriting discounts and offering expenses) from our initial public offering ("IPO") in August 2021. We have no products approved for commercialization and have never generated any revenue from product sales.

All of our product candidates, other than adintrevimab, 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. Our expenses could increase substantially as we:

- initiate and conduct clinical trials of VYD222 or any other product candidate;
- develop product candidates in new indications or patient populations;
- continue to advance the preclinical development of product candidates and our preclinical and discovery programs, including development and screening of additional antibodies;
- seek regulatory authorization or 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;
- validate our commercial-scale cGMP manufacturing process;
- manufacture material under cGMP at our contracted manufacturing facilities for clinical trials and potential EUA, regulatory approval and commercial sales;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;
- establish a sales, marketing and distribution infrastructure 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.

All of our product candidates, other than adintrevimab, are in clinical or preclinical development. 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 in a manner that keeps pace with the viral evolution, including completing preclinical testing and clinical trials of our product candidates, validating manufacturing processes, obtaining regulatory approval or EUA, and manufacturing, distributing, marketing, and selling any product candidates for which we may obtain regulatory approval or EUA, as well as

discovering and developing additional product candidates. 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 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, and developing and manufacturing our clinical and preclinical product candidates, including undertaking preclinical studies, developing and validating our manufacturing process, and conducting clinical trials. To date, we have not yet demonstrated our ability to obtain regulatory approvals or an EUA, or conduct sales and marketing activities necessary for successful commercialization, and we may not be successful in doing so. Additionally, if we submit a request for an EUA or submit an application for regulatory approval for any product candidate, we may not be successful in receiving such EUA or regulatory approval. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

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

We maintain our cash at financial institutions, often in balances that exceed federally insured limits.

The majority of our cash is held in accounts at U.S. banking institutions that we believe are of high quality. Cash held in depository accounts may exceed the $250,000 Federal Deposit Insurance Corporation (“FDIC”) insurance limits. If such banking institutions were to fail, such as Silicon Valley Bank when the FDIC took control in March 2023, we could lose all or a portion of those amounts held in excess of such insurance limitations. In the future, our access to our cash in amounts adequate to finance our operations could be significantly impaired by the financial institutions with which we have arrangements directly facing liquidity constraints or failures. Any material loss that we may experience in the future could have a material adverse effect on our financial condition and could materially impact our ability to pay our operational expenses or make other payments.

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

Our operations have consumed substantial amounts of cash since inception, and we expect to continue to incur significant expenses and operating losses over the next several years as we continue to develop our product candidate pipeline and build out our manufacturing capabilities for our product candidates, which, if authorized or 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 or an EUA for any product candidate that we develop or otherwise acquire, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of December 31, 2022, we had cash, cash equivalents and marketable securities of $372.0 million. As of March 23, 2023, we believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2024. This estimate is based on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. We plan to use our cash, cash equivalents and marketable securities to fund clinical development, manufacturing supply and initial commercialization costs for our product candidates, to fund clinical development and manufacturing supply costs of our next generation of antibody candidates to treat and prevent COVID-19, for the development of additional programs in our pipeline and for working capital

and other general corporate purposes. Our existing cash, cash equivalents and marketable securities may not be sufficient to fund any of our product candidates through regulatory approval or EUA. 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 our product candidates;
- the scope, progress, results and costs of discovery, non-clinical studies, preclinical development, laboratory testing and clinical trials for our 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 of manufacturing and validation activities associated with our current product candidates and with the development and manufacturing of 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 for any product candidates for which we may obtain regulatory approval or EUA;
- the timing and costs of securing sufficient capacity for clinical and commercial supply of our potential future 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 U.S. 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 or EUA;
- 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, including higher inflation rates, changes in interest rates and the recent disruptions to and volatility in the credit and financial markets in the U.S. and worldwide resulting, in part, from the 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 when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Risks Related to the Development of our Product Candidates

Newly emerging and future SARS-CoV-2 VoCs could reduce the activity and effectiveness of antibodies as a potential prevention of or treatment for symptomatic COVID-19, which may significantly and adversely affect our ability to complete our clinical trials, obtain authorization or approval of, and commercialize our product candidates.

Our primary focus since inception has been the development of antibodies against COVID-19. Multiple variants of the virus that cause COVID-19 have been documented in the U.S. and globally during the COVID-19 pandemic and newly emerging and future SARS-CoV-2 variants could reduce the activity and effectiveness of antibodies as a potential prevention of or treatment for symptomatic COVID-19. For example, although pre-clinical studies showed that adintrevimab had the potential to broadly neutralize SARS-CoV-2 and the previously predominantly circulating variants, including Alpha, Beta, Delta, and Gamma, *in vitro* analyses to evaluate neutralizing activity of adintrevimab against the Omicron variant and its sublineages generated data showing reduced neutralizing activity of adintrevimab against the Omicron BA.1 and BA.1.1 sublineages compared to a reference strain and a lack of neutralizing activity against Omicron BA.2. As a result, we paused enrollment in adintrevimab's Phase 2/3 trials in January 2022, which were subsequently closed, and we paused submission of an EUA request. While we intend to continue to monitor the evolution of SARS-CoV-2 and the *in vitro* activity of adintrevimab against predominant variants in the U.S. to identify a potential opportunity for an EUA request, we cannot be certain that adintrevimab will neutralize future variants and that we will submit an EUA for adintrevimab or whether an EUA will be granted if we do submit such request.

Our current lead product candidate, VYD222, is an engineered version of adintrevimab, which we have modified to improve binding to the Omicron variant and its sublineages. Based on *in vitro* analyses, we believe such modifications may be able to enhance neutralization potency against current and future novel variants, but such efforts may not be successful against newly emerging or future variants, in order to support an EUA or regulatory approval. Additionally, it is possible that *in vivo* analyses undertaken in the future may not be consistent with *in vitro* analyses. New SARS-CoV-2 variants could be less susceptible to such modifications and their mechanisms of action, or the results shown in pre-clinical studies may not be replicated in clinical trials. Additionally, it is possible that even if a product candidate showed *in vitro* neutralizing activity against the predominant SARS-CoV-2 variant at the initiation of a clinical trial, the predominant circulating variant may evolve and neutralizing activity of the candidate become reduced or negligible during the course of a clinical trial or at the time of EUA or other regulatory submission. Further, we may not be able to address reductions in neutralization potency with adjustments to the dose or dosing frequency. This would significantly and adversely affect our ability to complete our clinical trials, obtain authorization or approval of and commercialize VYD222 or any future product candidates. In addition, if our planned dosing of VYD222 were to be increased in response to reduction in neutralizing activity against dominant circulating SARS-CoV-2 variants or for other reasons, it could impact drug supply and pricing, which could adversely affect our commercial prospects.

We may not be able to obtain an EUA from the FDA or comparable foreign regulators for adintrevimab, VYD222 or any other product candidate due to the emergence of variants, such as the Omicron variant and its sublineages, which have shown reduced in vitro susceptibility to adintrevimab.

While we intend to monitor the evolution of SARS-CoV-2 and the *in vitro* activity of adintrevimab against predominant variants in the U.S. to identify a potential opportunity for an EUA request for adintrevimab in the event of a susceptible variant, we cannot be certain that adintrevimab or other product candidates will neutralize future variants and that we will submit an EUA for any product candidate or whether an EUA will be granted if we do submit such request. Even if we obtain an EUA

from the FDA, the FDA may withdraw authorization based on changes in circulating variants and subvariants for which our product candidates may not be effective.

All of our product candidates, other than adintrevimab, 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 or authorized for commercial sale, and all of our product candidates, other than adintrevimab, are currently in clinical and preclinical development. In February 2021, we initiated a Phase 1 clinical trial evaluating adintrevimab. We advanced adintrevimab into global Phase 2/3 trials for the prevention and treatment of COVID-19 and reported preliminary safety and efficacy data (pre-Omicron) for both trials in March 2022. However, based on feedback from the FDA regarding adintrevimab's lack of neutralizing activity against the Omicron BA.2 variant, we paused the submission of an EUA request and we have closed such trials. We plan to initiate clinical trials with our current lead candidate, VYD222, during the first quarter of 2023. While we believe that the adintrevimab clinical data package has the potential to support accelerated development of VYD222, the FDA may not accept our adintrevimab clinical data package in support of VYD222 approval or may identify issues with or challenge the adintrevimab clinical data package, which has not yet been reviewed. Furthermore, we have limited experience in preparing, submitting and prosecuting regulatory filings and have not previously submitted a BLA for any product candidate.

Our ability to generate revenue from our product candidates, which may not occur for several years, if ever, will depend heavily on the successful development, regulatory approval or granting of EUA for the prevention and/or treatment of COVID-19, obtaining of manufacturing supply, capacity and expertise and eventual commercialization of our product candidates. In the absence of an EUA declaration and determination issued under the FDCA, we will not be able to receive an EUA. The success of VYD222, adintrevimab or any other product candidates that we develop or otherwise may acquire will depend on many factors, including:

- the status of emerging variants where VYD222, adintrevimab or any other product candidate has limited to no activity against the virus;
- future SARS-CoV-2 VoCs could reduce the activity and effectiveness of antibodies as a potential prevention of or treatment for symptomatic COVID-19 and we may not be successful in timely identifying new antibodies that are suitable either as monotherapy or as combination therapy to mitigate the risk of reduced activity against future SARS-CoV-2 variants;
- the continuing need for therapies for the prevention and treatment of COVID-19, including due to the continuation and severity of the pandemic, the development of SARS-CoV-2 into an endemic disease or the inability of other available therapies to address COVID-19;
- the timing and progress of discovery, preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to successfully work with the FDA, EMA or other regulatory authorities to align on an expedited and replicable pathway to SARS-CoV-2 mAb authorization or approval, and the evolution of regulatory paradigms, which may rely on surrogate endpoints, to expedite drug development;
- filing acceptable IND applications with the FDA, or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- our ability to reach agreement with the FDA, EMA or other regulatory authorities as to the design or implementation of our clinical trials, including whether serum neutralizing antibody titers may be utilized as a correlate of protection in clinical trials for VYD222 or other product candidates;
- the sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials, manufacture the product candidates and complete associated regulatory activities;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing and successfully develop, obtain regulatory approval or EUA for, and then successfully commercialize our product candidates;
- successful enrollment and timely completion of clinical trials, including our ability to generate positive data from any such clinical trials;

- the costs associated with the discovery and development of any additional development programs and product candidates we identify in-house or acquire through collaborations;
- receipt of timely marketing approvals or EUAs from applicable regulatory authorities;
- developing and expanding sales, marketing and distribution capabilities and launching commercial sales of products, if approved or an EUA is obtained, whether alone or in collaboration with others;
- our ability to secure and maintain required state licenses for distribution of our products, if authorized or approved or an EUA is obtained, or other distribution disruptions;
- acceptance of the benefits and use of our products, including method of administration, if approved, by patients, the medical community and third-party payors, for their approved indications;
- the prevalence and severity of adverse events experienced with our product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative therapies for any product candidate that we develop;
- the availability and sufficiency of government funding for the purchase and/or reimbursement of products for the diagnosis, prevention and treatment of COVID-19, including competition against any products with government APAs and whether we are able to enter into any APAs if any of our product candidates are authorized or approved;
- our ability to obtain and maintain coverage and adequate reimbursement for our product candidates, if authorized or approved, 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;
- 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 approved or an EUA is obtained, and otherwise protecting our rights in our intellectual property portfolio;
- our ability to maintain compliance with regulatory requirements, current cGCP, cGLP, and cGMP, 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 or EUA; and
- the impact of any business interruptions to our operations or those of third parties with which we work, particularly in light of the COVID-19 pandemic or other similar public health crises.

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 approval or EUA for any product candidate we develop, we may not be able to continue our operations.

Because our product candidates represent novel approaches to the prevention and treatment of disease, there are many uncertainties regarding the development, market acceptance, third-party reimbursement coverage and commercial potential of our product candidates. We may not be successful in aligning with regulators on an expedited and replicable pathway to SARS-CoV-2 mAb authorization or approval.

COVID-19 is a relatively new disease and the prevention and treatment of this disease is evolving. Another party may be successful in producing a more efficacious prophylaxis or treatment for COVID-19, which may make it more difficult for us to obtain funding or lead to decreased demand for our potential products. Many small and large companies are developing therapies for the prevention and/or treatment of COVID-19, including antibodies, vaccines, antivirals, and other products. Some of these are being marketed and others are further along in the development and commercialization process than we are and several of these companies have access to larger pools of capital, including government funding, and broader infrastructure

that may make them more successful at developing, manufacturing or commercializing their products globally for the prevention and/or treatment of COVID-19. The success or failure of other companies, or perceived success or failure, may impact our ability to obtain future funding or to successfully commercialize our products for COVID-19 prevention and/or treatment.

To date no monoclonal antibody has been approved for prevention (pre- or post-exposure) or treatment of COVID-19 in the U.S. The FDA issued an EUA for tixagevimab/ cilgavimab for pre-exposure prophylaxis of COVID-19, in addition to EUAs for casirivimab/imdevimab and bamlanivimab/etesevimab for post-exposure prophylaxis of COVID-19 in certain individuals. In addition, four monoclonal antibody products, casirivimab/imdevimab, bamlanivimab/etesevimab, sotrovimab, and bebtelovimab have received an EUA from the FDA for the treatment of COVID-19 in patients at high risk of disease progression. However, the clinical utility of these products has varied over time due to the emergence of SARS-CoV-2 variants demonstrating partial or full resistance to neutralization and at this time none of these products are authorized for use in prevention or treatment of COVID-19 in the U.S. due to limited to no activity against the predominant circulating Omicron sublineages.

Because the use of engineered monoclonal antibodies is a relatively new and expanding area of novel therapeutic interventions, there are many uncertainties related to development, marketing, reimbursement and the commercial potential for our product candidates. There can be no assurance as to the length of the clinical trials, the number of patients the FDA or other comparable foreign regulatory authorities will require to be enrolled in the trials in order to establish the safety, efficacy, purity and potency of antibody products or that the design of or data generated in these trials will be acceptable to the FDA or other comparable foreign regulatory authorities to support EUA, or similar authorization outside of the U.S., or marketing approval. While we continue to work with global regulators to align on an expedited and replicable pathway to SARS-CoV-2 mAb authorization or approval and leverage evolving regulatory paradigms, which may rely on surrogate endpoints (including use of serum neutralizing antibody titers as a correlate of protection in clinical trials), to expedite drug development, there can be no guarantee that our efforts will be successful.

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

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

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

There is no assurance that the approaches offered by our product candidates will gain broad acceptance among healthcare practitioners 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. 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.

Our integrated discovery platform approach may not produce durable, broadly neutralizing, effective or safe antibodies in an adequate time period to address a changing virus. If we are unable to timely identify, develop, obtain

authorization or approval for, and commercialize antibodies on a perpetual, ongoing basis that keep pace with viral evolution, our business prospects will be significantly harmed.

We intend to deliver new product candidates on a perpetual, ongoing basis to provide solutions for vulnerable people as new VoCs emerge. Our integrated discovery platform approach is designed to produce candidate antibodies providing broad *in vitro* neutralization against past and current VoCs and their sublineages. However, we may not be successful in developing product candidates, or developing product candidates in an adequate time period, to target a changing virus. If we do develop product candidates, they may not be durable enough to increase the probability of providing a longer period of protection than other antibody solutions or be high-functioning and long-lasting with a high barrier to viral escape. Antibodies may not be effective or safe to administer prior to exposure to SARS-CoV-2 to prevent disease or, once sick, to treat disease. Furthermore, if we are unable to timely identify, develop, obtain authorization or approval for, and commercialize antibodies on a perpetual, ongoing basis that keep pace with viral evolution, our business prospects will be significantly harmed.

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 EUAs, 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, other than adintrevimab, are in clinical and preclinical development and their risk of failure is high. The clinical trials and manufacturing of our product candidates are, and the manufacturing and marketing of our products, if approved, will be, subject to extensive and rigorous review and regulation by numerous government authorities in the U.S. 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, and we could encounter problems that cause us to abandon or repeat clinical trials. Even if our future clinical trials are completed as planned, we cannot be certain that their results will support the safety and effectiveness of our product candidates for their targeted indications or support continued clinical development of such product candidates. Our current or future clinical trial results may not be successful.

In addition, even if such trials are successfully completed, we cannot guarantee that the FDA, the 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, 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 have and 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 have and may again in the future experience delays in conducting clinical trials, and we do not know whether our clinical trials will begin on time, need to be redesigned, recruit and enroll patients on time or be completed on schedule, or at all. We may experience numerous unforeseen events before, during or after the conduct of our clinical trials that could delay or prevent our ability to complete such trials or receive marketing approval for or commercialize our product candidates, or that could significantly increase the cost of such trials, including:

- inability to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation of clinical trials;
- delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials;
- delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates;
- delays in reaching agreement with the FDA, EMA or other regulatory authorities as to the design or implementation of our clinical trials, including whether serum neutralizing antibody titers may be utilized as a correlate of protection in clinical trials for VYD222 or other product candidates;
- delays in obtaining regulatory authorization to commence a clinical trial;
- challenges in reaching an agreement on acceptable terms with clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites;
- delays in obtaining IRB approval at each trial site;
- challenges in recruiting suitable patients to participate in a clinical trial;
- challenges in having patients complete a clinical trial or return for post-treatment follow-up;
- findings from 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, including as a result of changing standards of care or the ineligibility of a site to participate;
- failure to perform in accordance with the applicable regulatory requirements, including the FDA's regulations and cGCP 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;
- the evolution of SARS-CoV-2 variants during the course of a clinical trial may adversely impact the neutralizing activity of our product candidates and our ability to complete the trial if the potential benefits are no longer determined to outweigh the potential risks of any such product candidate as a result of reduced neutralizing activity against circulating SARS-CoV-2 variants;
- inability to recruit and/or successfully contract with a sufficient number of clinical trial sites;
- difficulties in manufacturing sufficient quantities of product candidate for use in clinical trials, including as a result of supply chain challenges or otherwise;
- suspensions or terminations by IRBs at the institutions where 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;
- 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 or superiority trials or the sample size needs to be increased based on the outcome rates observed during early trial conduct, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- enrollment in clinical trials may be impacted by the emergence of variants and rate of infection prevalence in the relevant communities, which can change once a trial is initiated;
- the evolution of SARS-CoV-2 variants during the course of a clinical trial may impact the prevalent variant of infection for patients at one or more sites and adversely impact enrollment potential;
- the screen failure rate for clinical trials of our product candidates may be higher than we anticipate, requiring us to screen larger numbers of patients than originally planned;
- the need to modify a trial protocol;
- unforeseen safety issues;
- emergence of dosing issues;
- lack of effectiveness data during clinical trials;
- changes in the standard of care of the indication being studied;
- 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;
- we conducted our STAMP trial (evaluating adintrevimab for the treatment of COVID-19) at sites outside of the U.S.; in the future, the applicable foreign regulatory authorities may determine that a placebo-controlled trial would expose patients to unacceptable health risks (because alternative effective therapies are or may become available in these regions during the conduct of the trial), which could delay enrollment of a trial and the authorization or approval of our products;
- 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.

We, the FDA, other regulatory authorities outside the U.S. or an IRB may suspend a clinical trial at any time for various reasons, including if it appears that the clinical trial is exposing participants to unacceptable health risks, including, for example, because the predominant SARS-CoV-2 variant in the country or clinical trial site is not susceptible to our product candidate, or if the FDA or one or more other regulatory authorities outside the U.S. find deficiencies in our IND or similar application outside the U.S. or the conduct of the trial. If we experience delays in the completion of, or the termination of, any clinical trial of any of our product candidates, the commercial prospects of such product candidate will be harmed, and our ability to generate product revenues from such product candidate will be delayed or rendered impossible. In addition, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process, and jeopardize our ability to commence product sales and generate revenues.

All of our product candidates will require extensive clinical testing before we would be in a position to submit a BLA to the FDA or MAA) to the EMA 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, if at all, or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, EMA or other regulatory authorities on our clinical development program, and the FDA, EMA or other regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs.

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

There can be no assurance that the public health emergency in the U.S. declared under the PHS Act and the FDCA will continue to be in place for an extended period of time and that the product candidates we are developing for COVID-19 could be granted an EUA by the FDA or similar authorization by regulatory authorities outside of the U.S. 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 candidates in the near future and instead, would need to pursue the traditional regulatory approval processes of the FDA and comparable foreign authorities, which are lengthy, time consuming and inherently unpredictable, and which we may determine not to pursue. If we are not able to obtain required regulatory authorization or approval for our product candidates, our business will be substantially harmed. We also cannot guarantee how long it will take regulatory agencies to review our EUA applications, if submitted, for our product candidates.

We intend to seek an EUA for the prevention and/or treatment of COVID-19 from the FDA and may seek similar authorization from regulatory authorities outside of the U.S., such as conditional marketing authorization from the European Commission. If we apply for an EUA and it is granted, an EUA will authorize us to market and sell our COVID-19 monoclonal antibody in the U.S. under certain conditions of authorization as long as a public health emergency declared under the FDCA

exists. The FDA may issue an EUA during a public health emergency declared under the FDCA 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 for VYD222, adintrevimab or any other product candidates, or other similar authorization or, if we do apply, that we will be able to obtain an EUA or such similar 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. The FDA may terminate an EUA if safety issues or other concerns about our product, such as loss of neutralizing activity against dominant circulating SARS-CoV-2 variants, arise or if we fail to comply with the conditions of authorization. Additionally, the FDA has expected that companies that receive an EUA for COVID-19 antibodies will proceed to licensure of their products under a full BLA. Accordingly, as we do not intend to pursue a BLA for VYD222 or potentially for other product candidates for COVID-19 given the SARS-CoV-2 variants, and if we determine not to pursue a BLA, this may adversely affect our ability to obtain or maintain an EUA in the U.S.

On January 30, 2023, the Biden Administration announced that it would allow the COVID-19 public health emergency in the U.S. declared under the Public Health Service Act to expire on May 11, 2023, which will have significant impacts on the U.S. health system and government operations. Although statements from HHS indicate that the FDA's EUAs for COVID-19 products will not be affected and that the FDA may continue to issue new EUAs going forward when criteria for issuance are met, as permitted due to the COVID-19 public health emergency in the U.S. declared under the FDCA, it is not clear if and under what circumstances the FDA will be willing to issue additional EUAs related to COVID-19 and we cannot predict how this may impact our ability to obtain or maintain an EUA if we apply for one. For example, the FDA issued a notice on March 13, 2023 stating that several guidance documents related to the development of products intended for the treatment or prevention of COVID-19 will be revised within 180 days of the expiration of the COVID-19 public health emergency and that such revised guidance documents will supersede the currently in-effect guidance documents. As such, it remains unclear what FDA's expectations will be going forward for EUA (and full licensure) for products intended for the treatment or prevention of COVID-19. Additionally, if the HHS Secretary terminates an EUA declaration under the FDCA, then any EUAs issued based on that declaration will cease to be in effect, and FDA may no longer issue EUAs for products covered by that declaration. Accordingly, even if we apply and obtain an EUA from the FDA, there is no guarantee of the duration for which we would be able to maintain it.

If we apply for an EUA or similar authorization from regulatory authorities outside of the U.S., 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 authorization or approval for any product candidate, and it is possible that we may never obtain regulatory authorization or 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 U.S. until we receive regulatory authorization with an EUA or approval of a BLA from the FDA, and we cannot market it in the European Union until we receive marketing authorization from the EMA, or other required regulatory approval in other countries. In the past, we have had discussions focused on adintrevimab with the FDA and Health Canada and have received scientific advice from the Medicines and Healthcare products Regulatory Agency, the Swedish Medical Products Agency, the Paul Ehrlich Institute, and the EMA regarding clinical development programs or regulatory approval for any product candidate within the U.S., Canada, United Kingdom, Sweden, Germany and European Union, respectively. We have had no discussions with other comparable foreign authorities regarding clinical development programs or regulatory approval for any product candidate outside of these jurisdictions.

Prior to obtaining approval to commercialize any drug product candidate in the U.S. 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 candidate is 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, including whether we may rely on surrogate endpoints in our clinical trials (including use of serum neutralizing antibody titers as a correlate of protection in clinical trials for VYD222 or other product candidates), or with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- we may be unable to collect sufficient data from clinical trials of our product candidates to support the submission and filing of a BLA with the FDA, MAA with the EMA or other submission;
- we may fail bioresearch monitoring, FDA inspection or comparable foreign regulatory authorities' inspection;
- we may fail an FDA or comparable foreign regulatory authorities' inspection of our third-party contract manufacturing or testing facilities for which we contract and test clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may find our contract manufacturing related activities (e.g., process validation, product characterization, product stability and expiry, and comparability establishment) insufficient for approval; and
- the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

From time to time, we may publicly disclose 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.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. 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 authorization or approval for, and commercialize, VYD222, adintrevimab and any other 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 authorization or 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 authorizations or approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved.

We may fail to demonstrate with substantial evidence from adequate and well-controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and effective for their intended uses. In addition, the FDA or comparable foreign regulatory authorities may determine that antibody monotherapy products are not sufficient and that combination antibody therapies should become the standard of care. For example, the clinical data available from the STAMP (evaluating adintrevimab for the treatment of COVID-19) and EVADE (evaluating adintrevimab for the prevention of COVID-19) trials may be insufficient to support a BLA or marketing authorization for adintrevimab and we may not be able to generate additional data if the FDA or comparable foreign regulatory authorities require additional trials in support of a BLA or marketing authorization. Additionally, while we believe that the adintrevimab clinical data package has the potential to support accelerated development of VYD222, the FDA may not accept our adintrevimab clinical data package in support of VYD222 approval or may identify issues with or challenge the adintrevimab clinical data package, which has not yet been reviewed, which may delay the development or potential commercialization of VYD222.

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

If any such adverse events occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that any adverse events were not caused by the drug, the FDA, EMA or foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidates for any or all targeted indications, or require that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates that we have not planned or

anticipated. Side effects may also lead regulatory authorities to require stronger product warnings on the product label, costly post-marketing studies, and/or a REMS, among other possible requirements. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the product candidate. Even if we are able to demonstrate that all future serious adverse events are not product-related, such occurrences could affect patient recruitment or the ability of enrolled patients to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates and may harm our business, financial condition and prospects significantly.

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

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

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

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

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

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

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

Successful and timely completion of clinical trials will require that we enroll, and maintain the enrollment of, a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors that

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

Further, we may determine that enrollment in a clinical trial should be paused, delayed or terminated in order to revise trial protocols in light of preliminary data generated by the trial or new data generated in other studies. For example, following our review of data generated in external *in vitro* analyses examining the neutralizing activity of adintrevimab against the Omicron SARS-CoV-2 BA.1 variant in both authentic and pseudovirus assays, in January 2022 we paused enrollment of new patients in both our EVADE (evaluating adintrevimab for the prevention of COVID-19) and STAMP (evaluating adintrevimab for the treatment of COVID-19) clinical trials to assess dosing strategy and revise our trial protocols in light of the global spread of the Omicron variant and its sublineages; we reported preliminary safety and efficacy data from both trials in March 2022, but as a result of the lack of neutralizing activity against the Omicron BA.2 variant, we paused the submission of an EUA request, and we have closed such trials. Trials may also 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;
- the impact infection prevalence may have on enrollment, as well as the emergence and evolution of SARS-CoV-2 variants, which may impact the prevalent variant of infection for patients at one or more clinical trial sites and adversely impact enrollment potential;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the trial protocol, including but not limited to the use of a placebo control or active comparator;
- the perceived risks and benefits of the product candidate in the trial, including relating to monoclonal antibody and/or vaccine approaches;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation;
- the willingness of patients to be enrolled in our clinical trials;
- the ability to obtain and maintain subject consents;
- local, national and/or employer COVID-19 vaccine mandates;
- the efforts to facilitate timely enrollment in clinical trials;
- potential disruptions caused by the COVID-19 pandemic, including difficulties in initiating clinical sites, enrolling and retaining participants, diversion of healthcare resources away from clinical trials, vaccine mandate policies, travel or quarantine policies that may be implemented, our ability to import and export clinical trial supplies, raw materials and commercial supply and other factors;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the risk that subjects enrolled in our clinical trials will drop out of the trials before completion; and
- the proximity and availability of clinical trial sites for prospective patients.

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

Breakthrough therapy designation in the U.S. or the equivalent thereof in foreign jurisdictions (where available) 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 in the U.S., if we determine to pursue a BLA, 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 determine to pursue a BLA and 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 focused on advancing antibodies into clinical trials for the prevention and treatment of COVID-19 and other infectious diseases. 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 U.S., and the FDA and similar foreign regulatory authorities may not accept data from such trials conducted in locations outside of their jurisdiction.

We plan to conduct and may in the future conduct additional clinical trials for our product candidates outside the U.S. The acceptance of trial data from clinical trials conducted outside the U.S. by the FDA may be subject to certain conditions or may not be accepted at all. For example, in order for the FDA to accept a foreign clinical trial as support for an investigational new drug application or application for marketing approval, the FDA requires the following conditions are met: (i) the trial was conducted in accordance with cGCP standards, and (ii) the FDA is able to validate the data from the trial through an onsite inspection if the FDA deems it necessary. 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 U.S. 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 through internal efforts or through partnerships for discovery of novel antibody 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 authorization or approval and achieve market acceptance. Further, even if we obtain authorization or approval for a product candidate for one indication that

may have potential for new or additional indications, we may determine that those additional indications are not worth pursuing for strategic reasons, including new legislation that may impact our ability to commercialize such compounds for such indications, if approved. 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 COVID-19 pandemic.

The evolving and constantly changing impact of COVID-19, which was declared a global pandemic by the WHO in March 2020, will directly affect the potential commercial prospects of our product candidates for the prevention and treatment of COVID-19. The severity of the disease and the global pandemic, the availability, administration and acceptance of vaccines, monoclonal antibodies, antiviral agents and other therapies, potential vaccine mandate policies, and the potential development of "herd immunity" by the global population will affect the design and enrollment of our clinical trials, the potential regulatory authorization or approval of our product candidates and the commercialization of our product candidates, if authorized or 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 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 as well as our clinical programs and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. Further, such orders also may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities. Additionally, on September 9, 2021, President Biden issued an executive order obligating parties that contract with the federal government to require their employees to be fully vaccinated against COVID-19, with limited exceptions for certain accommodations, and on November 5, 2021 the Department of Labor's Occupational Safety and Health Administration ("OSHA") issued an emergency temporary standard (the "ETS") requiring all private employers with 100 or more workers to mandate COVID-19 vaccination or produce a weekly test for all employees. Although the executive order has been the subject of legal challenges and is currently enjoined nationwide, there can be no assurance that the executive order will not be upheld and enforced or that President Biden will not issue another executive order. Further, while the ETS was withdrawn effective January 26, 2022, OSHA has not withdrawn the ETS as a proposed rule. As a company that is likely to have 100 employees at the time such rule may become a final standard, we would be required to mandate COVID-19 vaccination of our workforce or require our unvaccinated employees to be tested weekly if the proposed rule becomes a final standard or if the executive order is upheld in the courts and we were to contract with the federal government. We or our suppliers may incur increased costs, labor disruptions or employee attrition as a result of these or similar mandates. If we or other companies in our supply chain lose employees, it may be difficult in the current competitive labor market to find replacement employees, and this could have a material adverse effect on our business and results of operations.

To date, we have experienced some delays in our development activities as a result of the COVID-19 pandemic. In the future, we anticipate there could be additional or even significant disruptions, delays or uncertainties in our development activities as a result of the COVID-19 pandemic, including the ongoing shutdowns in China, as outbreaks occur and progress and some of our CROs, CDMOs and other service providers continue to be impacted. In December 2020, shipment of adintrevimab clinical supply by WuXi Biologics 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;
- interruption in clinical trial enrollment due to emergence of variant(s) against which VYD222 or any other product candidate is not anticipated to have activity;
- interruptions in our ability to manufacture and deliver drug supply for trials due to capacity constraints or lack of raw materials;
- interruptions to our ability to supply clinical trial material to clinical trial sites due to supply chain challenges;

- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- changes in local regulations (including potential vaccine mandates) as part of a response to the COVID-19 outbreak that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- uncertainty around patient enrollment rates due to unpredictable and variable regional rates of infection;
- limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA and other regulatory authorities to accept data from clinical trials in these affected geographies.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

The global COVID-19 pandemic continues to rapidly evolve, particularly with regard to the rapid global spread of the Omicron variant and its sublineages. The extent to which the COVID-19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence as of the date of this Annual Report, such as the ultimate geographic spread of the disease and the neutralizing activity of VYD222, adintrevimab and any other product candidates against the dominant circulating variant(s) at any given time, the duration of the outbreak, the duration and effect of business disruptions and the short-term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the U.S. 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 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.

We may develop VYD222, adintrevimab and future product candidates for use in combination with other therapies or third-party product candidates, which exposes us to additional regulatory risks.

We may develop VYD222, adintrevimab and future product candidates for use in combination with one or more currently authorized or approved therapies to prevent or treat COVID-19, or with therapies that may be authorized or approved in the future. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA, EMA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. Combination antibody therapies appear to be favored by the FDA over monotherapy for the prevention and treatment of COVID-19, and in the future the FDA, EMA and comparable foreign regulatory authorities may determine that monotherapy products should not be approved for the prevention or treatment of COVID-19, eliminating our ability to commercialize VYD222, adintrevimab or any other product candidate as a monotherapy treatment for the prevention or treatment of COVID-19.

We may also evaluate VYD222, adintrevimab or any future product candidate in combination with one or more other third-party product candidates that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. If so, we will not be able to market and sell VYD222, adintrevimab or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or comparable foreign regulatory authorities do not approve these other product candidates, or revoke their approval of, or if safety, efficacy, manufacturing or supply issues arise with, the biologics or antivirals we choose to evaluate in combination with VYD222,

adintrevimab or any product candidate we develop, we may be unable to obtain approval of or market any such product candidate.

Even if our product candidates obtain regulatory approval, they may be negatively impacted by future development or regulatory difficulties.

Approved drug products are subject to ongoing regulatory requirements and oversight, including requirements related to manufacturing, quality control, further development, labeling, packaging, storage, distribution, safety surveillance, import, export, advertising, promotion, recordkeeping and reporting. In addition, we will be subject to continued compliance with cGMP and cGCP requirements for any clinical trials that we conduct post-approval. If we or any of the third parties on which we rely fail to meet those requirements, the FDA or comparable regulatory authorities outside the U.S. could initiate enforcement action. Other potential consequences include the issuance of fines, warning letters, untitled letters or holds on clinical trials, product seizure or detention or refusal to permit the import or export of our product candidates, permanent injunctions and consent decrees, or the imposition of civil or criminal penalties, any of which could significantly impair our ability to successfully commercialize a given product. If the FDA or a comparable regulatory authority outside the U.S. becomes aware of new safety information, it can impose additional restrictions on how the product is marketed or may seek to withdraw marketing approval altogether.

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

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 (the "Transition Period") during which European Union rules continued to apply. A trade and cooperation agreement (the "Trade Cooperation Agreement") that outlines the post-Transition Period trading relationship between the United Kingdom and the European Union was agreed to in December 2020 and was formally entered into on May 1, 2021.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from European Union directives and regulations, Brexit has had, and will continue to have, a material impact on the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom. For example, Great Britain (England, Scotland and Wales) is no longer covered by the centralized procedures for obtaining European Union-wide marketing authorizations from the European Commission, and a separate marketing authorization is required to market our product candidates in Great Britain. Northern Ireland, however, continues to be covered by the marketing authorizations granted by the European Commission, but this is expected to change so that Northern Ireland would be subject to the same MHRA authorization procedures as Great Britain if the Windsor Framework announced by the United Kingdom government on February 27, 2023 is approved. All of these changes could increase our costs and otherwise adversely affect our business. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would delay or prevent us from commercializing our product candidates in the United Kingdom and limit our ability to generate revenue and achieve and sustain profitability. The Annex to the Trade and Cooperation Agreement further provides a framework for the recognition of cGMP inspections and for the exchange and acceptance of official cGMP documents. The regime does not, however, extended to procedures such as batch release certification. Among the changes that have occurred are that Great Britain (England, Scotland and Wales) is treated as a "third country," a country that is not a member of the European Union and whose citizens do not enjoy the European Union right to free movement. Northern Ireland continues to follow many aspects of the European Union regulatory rules, particularly in relation to trade in goods. As part of the Trade and Cooperation Agreement, the European Union and the United Kingdom recognize cGMP inspections carried out by the other party and the acceptance of official cGMP documents issued by the other party. The Trade and Cooperation Agreement also encourages, although it does not oblige, the parties to consult one another on proposals to introduce significant changes to technical regulations or inspection procedures. Among the areas of absence of mutual recognition are batch testing and batch release. The United Kingdom has unilaterally agreed to accept European Union batch testing and batch release, and any change to this position is subject to a minimum two year notice period. However, the European Union continues to apply European Union laws that require batch testing and batch release to take place in the European Union territory. This means that medicinal products that are tested and released in the United Kingdom must be retested and re-released when entering the European Union market for commercial use. While the Trade and Cooperation Agreement provides for the tariff-free trade of medicinal products between the United Kingdom and the European Union, there are additional non-tariff costs to such trade that did not exist prior to the end of the post-Brexit Transition Period. Further, should the United Kingdom diverge from the European Union from a regulatory perspective in relation to medicinal products, tariffs could be put into place in the future. We could therefore, both now and in the future, face significant additional expenses

(when compared to prior to the end of the Transition Period) 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, and we rely on contract manufacturers for access to capacity. We could experience manufacturing problems, may be unable to access desired manufacturing capacity within desired timeframes, or may be unable to access raw materials due to global supply chain shortages or otherwise, that result in delays in the development or commercialization of our product candidates or otherwise harm our business.

The manufacture of monoclonal antibody and other protein-based therapies are technically complex and necessitate substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical trials or commercialization efforts.

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

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

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

- a failure in the manufacturing process itself, for example by an error in manufacturing process, operator or human error, equipment failure, raw material or reagent failure, failure in any step of the manufacturing process, failure to maintain a cGMP environment or failure in quality systems applicable to manufacture (whether by us or our third-party contract development and manufacturing organization), sterility failures, testing failure or contamination during processing;
- a lack of reliability or reproducibility in the manufacturing process itself leading to variability in process execution or in product quality, which may lead to regulatory authorities placing a hold on a clinical trial or commercial supply and distribution or requesting further information on the process, which could in turn result in delays to the clinical trials or commercial supply and distributions;
- inability to obtain manufacturing or testing slots within desired timeframes from contract development and manufacturing organizations (including contract testing laboratories that perform cGMP operations), or CDMOs, or to have enough manufacturing slots to manufacture our product candidates to meet clinical or commercial requirements and demands;
- unfavorable FDA, EMA or other foreign or state regulatory inspection of the manufacturing or testing site;
- inability to procure raw materials and reagents due to global supply chain shortages or otherwise;

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

The regulatory authorities also may, at any time following approval of a product for sale, inspect or audit us or our CDMO's manufacturing facilities or those of our third-party contractors. If any such inspection or audit identifies a failure to comply with applicable regulations or if compliance discrepancies with our product specifications or violations of applicable regulations occur independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could harm our business. If we or any of our CDMOs fail to maintain regulatory compliance, the FDA or other regulatory authorities can impose regulatory sanctions, including, among other things, refusal to approve a pending application or to issue a positive opinion 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 depend on sole-source third-party suppliers for materials that are necessary for the conduct of preclinical studies and manufacture and testing of our product candidates for clinical trials, and the loss of these third-party suppliers and manufacturers or their inability to supply us with sufficient quantities of adequate materials, or to do so at acceptable quality levels and on a timely basis, could harm our business.

Manufacturing and testing our product candidates require many specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture and testing of our product candidates. For example, we are reliant on WuXi Biologics as the procurer of the raw materials used in the manufacture of our product candidates, including certain single-source purification resins and cell culture media, which increases the risk of delays in production. In addition, to date, we have relied on WuXi Biologics as our only CDMO. The loss of this CDMO or its failure to supply us with material to support our commercial 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 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 current or future CDMOs may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we or our current or future 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 current or future CDMOs rely on and may in the future rely on sole-source vendors or a limited number of vendors. The supply of specialty materials and equipment that are necessary to produce our product candidates could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier or manufacturer could result in delay, and we may not be able to find other acceptable suppliers or manufacturers on acceptable terms, or at all. Switching suppliers or manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If key suppliers or manufacturers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, test, manufacture and market our product candidates in a timely and competitive manner, or at all. An inability to continue to source product from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business.

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

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

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

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

Risks Related to the Commercialization of Our Product Candidates

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

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

- our ability to hire and retain a sales force in the U.S.;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for any product candidates, once authorized or 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 or combination therapy.

If we are unable to establish sales, marketing and distribution capabilities for VYD222, adintrevimab or any other product candidate that may receive regulatory authorization or approval, we may not be successful in commercializing those product candidates if and when they are authorized or approved.

We will need to establish a commercial infrastructure to support the anticipated marketing and distribution of our product candidates, which we will need to achieve commercial success for VYD222, adintrevimab or any other product candidate for which we may obtain authorization or marketing approval. There are risks involved with establishing our commercial infrastructure. For example, hiring a contract sales force or recruiting and training a sales force in the future is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we hire a contract sales force or 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 authorized or 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 product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

Our mission is to deliver antibody-based therapies that protect vulnerable people from the consequences of viral threats, beginning with COVID-19. Our projections of the number of people who are candidates to receive COVID-19 preventatives and treatments are estimates based on our knowledge and understanding of this disease. These estimates may prove to be incorrect and new studies may further reduce the estimated incidence or prevalence of this disease. The number of COVID-19 patients in the U.S., the European Union and elsewhere may turn out to be lower than expected, and patients may not be otherwise amenable to treatment with our product candidates or may become increasingly difficult to identify and access, all of which would adversely affect our financial condition, results of operations and prospects. Further, even if we obtain authorization or approval for our product candidates, the FDA or other regulators may limit their authorized or 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 COVID-19 pandemic, including disease due to variants with relative or absolute resistance to other products, or an increase in available alternative therapies for or widespread immunity to COVID-19, could reduce the total addressable market for our product candidates for the prevention and treatment of COVID-19. Similarly, if new SARS-CoV-2 variants are less impacted by our product candidates and their

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 our product candidates, if authorized or 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 on the final label, if approved for sale in specified indications, acceptance by the medical community, patient access, and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative. The process we have used in developing an estimated total addressable market range for the indications we are targeting has involved using a third party to model the future populations susceptible to and immune from SARS-CoV-2, based on assumptions such as vaccine adoption, efficacy, duration of effect, viral infectiousness and other factors we cannot control. Accordingly, these estimates included in this filing may turn out to be inaccurate. Further, the data and statistical information used in this Annual Report on Form 10-K, and in our other filings with the SEC, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

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 U.S. and any other jurisdiction for which we obtain an EUA or similar authorization or obtain regulatory approval and have commercial rights. If the markets or patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, even if approved.

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, the European Commission or other comparable foreign regulatory authorities, we may only promote or market our products for their specifically approved indications. We will train our marketing and sales force against promoting our products 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’. Furthermore, the use of our products for indications other than those authorized or approved by the FDA, European Commission or other comparable foreign regulatory authorities, may not effectively treat such conditions. Any such off-label use of our products 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 uses for which they are not authorized or 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 U.S. will be heavily scrutinized by the FDA, the FTC, the Department of Justice (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 U.S. 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 correct information to healthcare practitioners, injunctions, or civil or criminal penalties.

The advertising and promotion of our products in the European Union is subject to European Union Member States’ national laws implementing Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation of individual European Union Member State governing the advertising and promotion of medical devices. European Union Member States’ legislation may also restrict or impose limitations on our ability to advertise our products directly to the general public. In addition, voluntary European Union and national Codes of Conduct provide guidelines on the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals. Any actual or alleged failure to comply with promotion requirements may result in fines, warning letters, injunctions, or civil or criminal penalties.

VYD222, adintrevimab and other monoclonal antibody product candidates may face significant competition from vaccines, antiviral agents and other therapeutics for COVID-19 that are currently available or in development.

Many biotechnology and pharmaceutical companies are developing therapeutics for COVID-19 or vaccines against SARS-CoV-2, the virus that causes COVID-19. Many of these companies, which include large pharmaceutical companies, have greater resources for development and established commercialization capabilities. For example, the FDA has approved or granted EUA for several vaccines and therapeutics for the prevention or treatment of COVID-19 developed or marketed by other companies, many of which are large, established biotechnology and pharmaceutical companies. Many of these companies have also been successful in securing government funding to support research and development and/or manufacturing of their product candidates as well as government contracts to purchase their supply orders. Additional vaccines and therapeutics are

in development by other pharmaceutical and biopharmaceutical companies. Given the products currently approved or authorized for use as well as those in development by others, any therapies we may develop could face significant competition. If any other company develops therapeutics more rapidly or effectively than we do, develops a therapeutic that becomes the standard of care, develops a therapeutic at a lower cost or is more successful at commercializing an approved therapeutic, we may not be able to successfully commercialize VYD222, adintrevimab or any other product candidate for the prevention and treatment of symptomatic COVID-19, even if authorized or approved, or compete with other therapeutics or vaccines, which could adversely impact our business and operations.

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

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

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

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

Additionally, government entities, such as the CDC, NIH, the WHO and non-government professional societies, such as the IDSA and the European Society of Clinical Microbiology and Infectious Diseases (the “ESCMID”) may produce treatment and/or prevention guidelines for COVID-19, including the use of monoclonal antibodies for these indications. However, our monoclonal antibodies, even if authorized or approved, may fail to be added to such guidelines or receive poor positioning within such guidelines, which may instead recommend products of our competitors.

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.

Our COVID-19 product candidates may have to compete against products with APAs from the U. S. federal government.

In an EUA environment where the U.S. federal government contracting procedures generally involve signing an APA with a manufacturer for a specific number of doses at a fixed price, product distribution is overseen by federal and state governments and product is ordered by institutions, prescribed by physicians and administered in a variety of settings. Products

purchased and supplied under APAs are paid for by the U.S. federal government and are free to the institutions and patients, but patients can be billed for administration costs.

For example, currently, all oral antivirals are made available under APAs. Only Gilead's intravenous antiviral, remdesivir, which received full FDA approval for treatment of non-hospitalized patients (12 years of age or older) at high risk for COVID-19 progression in January 2022, is available under a standard purchase model where hospitals, clinics, and other institutions purchase product through distributors. In the past, the U.S. federal government also entered into APAs for monoclonal antibodies. However, in August 2022, HHS announced that Eli Lilly's bebtelovimab would be transitioning from an APA model to a traditional commercial model and since that time, there have been no new APAs signed for any COVID mAbs.

In this environment, there is the potential that the U.S. federal government will have or enter into APAs with our competitors but decide not to enter into a contract with us for the supply of any COVID-19 product for which we might obtain an EUA. U.S. federal government contracts require contractors to meet a substantial number of qualifications, and it is possible that we would not meet some or all of these qualifications, resulting in our inability to secure a federal contract. Additionally, our primary contract manufacturer is based in China. Given existing country-of-origin based restrictions applicable to federal procurement that prohibit, with limited exceptions, procurement of product that originates from China, it is possible that the U.S. federal government could decline to contract with us in light of the manufacturing of the drug substance for our product in China.

If any of our product candidates are authorized under an EUA, but do not receive an APA, utilization of our product may be limited if we are competing against products that are supplied under APAs.

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 VYD222 and adintrevimab, and the extent to which patients will be willing to pay out-of-pocket for such products, in the absence of reimbursement for all or part of the cost. In the U.S. 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 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 the IDSA and the ESCMID, may produce treatment and/or prevention guidelines for the prevention and treatment of COVID-19, including guidance regarding the use of monoclonal antibodies in these indications. If VYD222, adintrevimab or any other product candidate fails to be added to these guidelines, or if they receive poor positioning within these guidelines, payors and other customers may be less inclined to add VYD222, adintrevimab or any other product candidate to their formularies, significantly reducing demand for such product candidate, if approved.

Further, increasing efforts by third-party payors in the U.S. 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, if approved. 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 product 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. In many countries in the European Union, procedures to obtain price approvals, coverage and reimbursement can take considerable time after the receipt of marketing authorization. Many European countries periodically review their reimbursement of medicinal products, which could have an adverse impact on reimbursement status. In addition, we expect that legislators, policymakers and healthcare insurance funds in the European Union member states will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down. Moreover, in order to obtain reimbursement for our products in some European countries, including some European Union member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some European Union member states, including those representing the larger markets. The HTA process, which is currently governed by national laws in each European Union member state, is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual European Union member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between European Union member states, although the HTA Regulation which aims to harmonize the clinical benefit assessment of HTA across the European Union will apply beginning on January 12, 2025. If we are unable to obtain, then maintain favorable pricing and reimbursement status in European Union member states that represent significant markets, our anticipated revenue from and growth prospects for our products in the European Union could be negatively affected. Due to the evolving effects of the COVID-19 pandemic, we may anticipate delays by certain European regulatory authorities in their pricing and reimbursement reviews. If we experience setbacks or unforeseen difficulties in obtaining favorable pricing and reimbursement decisions, including as a result of regulatory review delays due to the COVID-19 pandemic, planned launches in the affected European Union member states would be delayed, which could negatively impact anticipated revenue from and growth prospects for VYD222, adintrevimab or any other product candidate.

There can be no assurance that VYD222, adintrevimab or any other product candidate, if approved for sale in the U.S. 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 U.S. 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.

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

In the future, if we determine to pursue and we are successful in achieving regulatory approval to commercialize any biologic product candidate that we develop, such approved product may face competition from biosimilar products. In the U.S., product candidates are regulated by the FDA as biologic products subject to approval under the BLA pathway. The ACA includes a subtitle called the 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 biological products.

There is a risk that any of our product candidates approved as a biological product under a BLA, should we determine in the future to pursue such regulatory pathway, would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. For example, in May 2021, the Biden administration expressed support for waiving intellectual property protections for COVID-19 vaccines amid concerns about vaccine access in foreign nations. Such waiver, if implemented, could extend to our product candidates. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of

our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. In the European Union, biosimilars can only be authorized once the period of data exclusivity on our candidate, as 'reference' biological medicinal product, has expired. In general, this means that the biological reference medicine must have been authorized for at least eight years before another company can apply for approval of a similar biological product. 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.

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. Side effects or adverse events known or reported to be associated with, or manufacturing defects in, the products sold by us could exacerbate a patient's condition, or could result in serious injury or impairment or even death. This could result in product liability claims against us and/or recalls of one or more of our products. In many countries, including in European Union member states, national laws provide for strict (no-fault) liability which applies even where damages are caused both by a defect in a product and by the act or omission of a third party. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

Maintaining the security of our information systems and communication systems is a critical issue for us, and we devote considerable internal and external resources to network security and other security measures to protect our systems and users, but these security measures cannot provide absolute security. Moreover, even security measures that are deemed appropriate, reasonable, and/or in accordance with applicable legal requirements may not be able to protect the information we maintain. The multitude and complexity of our information systems may furthermore make them susceptible to service interruption, breaches of security, disruption of data integrity, inadvertent errors that expose our data or systems, malicious intrusion, or cyberattacks. Despite our efforts, the possibility of these events occurring, and the ever-changing threat landscape, cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber-attacks or security breaches that could adversely affect our business.

Our internal information systems, and those of third parties on which we rely, are also vulnerable to, among other things, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, system malfunctions, cyberattacks or cyber-intrusions over the Internet, and phishing attacks. The source of these vulnerabilities may be persons inside or outside our organization. We have in the past and plan to in the future identify defects, errors, or vulnerabilities, which could inadvertently permit access to or exposure of data, including personal information, that we maintain or which third parties maintain on our behalf. The risk of a cybersecurity incident, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. For example, the ongoing conflict between Russia and Ukraine has led to an increase in cyberattacks on the Ukraine, including its government, companies, institutions and people, as well on the financial and communications infrastructure of other countries, companies and individuals therein. If any such

event were to occur in countries in which we operate, 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 or alteration of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Additionally, such events could lead to an interruption in our supply chain for the manufacturing of clinical and commercial drug substance and drug product, as well as related materials, and could significantly impact development and commercialization timelines and capabilities. If our information systems or a third-party's information systems on which we rely suffer severe damage, disruption or shutdown and issues are not resolved in a timely manner, we could experience delays in reporting our financial results, and we may lose revenue and profits as a result of our inability to timely manufacture or distribute our products. We continue to implement security measures to bolster our network security and protect our systems, however, such efforts are not guaranteed to prevent such events from occurring.

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 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 information systems, or the information systems of other business partners, 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 information security failures or cybersecurity incidents attributed to our third-party service providers as they relate to the information we share with them.

Notifications and follow-up actions related to a data breach or other cybersecurity incident could impact our reputation and cause us to incur significant costs, including significant legal expenses and remediation costs as well as potential regulatory scrutiny. We expect to incur significant costs in an effort to detect and prevent cybersecurity incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived cybersecurity incident. However, we cannot guarantee that we will be able to detect or prevent any such cybersecurity 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 cybersecurity incidents. To the extent that any disruption or cybersecurity incident 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 reputational harm, penalties, regulatory scrutiny, liabilities, legal claims, and/or mandated changes in our business practices, and the further development of our product candidates could be delayed. Any such event could also compel us to comply with federal and state breach notification laws, and foreign law equivalents, subject us to mandatory corrective action and otherwise subject us to substantial liability under laws, rules, regulations and standards that protect the privacy and security of personal data, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

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

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

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. In the U.S., 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 U.S., 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 ("FTC 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 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder. HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their "business associates" – independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service for or on behalf of a covered entity. Depending on the facts and circumstances, we could be subject to significant penalties if we, our affiliates, or our agents knowingly receive individually identifiable health information maintained by a HIPAA-covered entity individually identifiable health information in a manner that is not authorized or permitted by HIPAA.

At the federal level, the FTC also sets expectations for failing to take appropriate steps to keep consumers' personal information secure, or failing to provide a level of security commensurate to promises made to individuals about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of the FTC Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations for failing to honor the privacy promises made to individuals about how the company handles consumers' personal information; such failure may also constitute unfair or deceptive acts or practices in violation of the FTC Act. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

In Europe, the GDPR governs the collection, use, disclosure, transfer or other processing of personal data of individuals within the European Economic Area ("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 includes notice and consent requirements which may apply to clinical trial subjects and investigators. In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA to the U.S. 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 U.S. by invalidating the EU-U.S. Privacy Shield and imposing further restrictions on the use of standard contractual clauses. The European Commission and the U.S. announced in March 2022 agreement in principle on a new Trans-Atlantic Data Privacy Framework with respect to data transfers to the U.S., and, on December 13, 2022, the European Commission adopted a draft adequacy decision for the EU-U.S. Data Privacy Framework. This draft decision follows the signature of a U.S. Executive Order by President Biden on October 7, 2022, along with the regulations issued by the U.S. Attorney General Merrick Garland. These two instruments implemented into U.S. law the agreement in principle announced by the President of the European Commission and President Biden in March 2022. The draft adequacy decision, which reflects the assessment by the European Commission of the US legal framework has now been published and transmitted to the European Data Protection Board ("EDPB") for its opinion. The draft decision concludes that the U.S. ensures an adequate level of protection for personal data transferred from the EU to U.S. companies. The GDPR imposes substantial fines for breaches and violations (up to the greater of €20 million or 4% of our annual global turnover) and confers the right for data subjects 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. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, which exposes us to further compliance risk. On June 28, 2021, the European Commission formally adopted its adequacy decision finding the United Kingdom to be adequate under the GDPR. Personal data may now flow freely from the EEA to the UK, however, the European Commission may suspend the Adequacy Decision if it considers that the UK no longer provides for an adequate level of data protection.

We have implemented data transfer policies to provide for the transfer of personal information from the EEA or the United Kingdom to the U.S. However, there are certain unsettled legal issues regarding the adequacy of data transfers to the U.S., the resolution of which may adversely affect our ability to process and transfer personal data outside of the EEA or United Kingdom. In October 2022, President Biden issued an executive order to implement EU-U.S. data privacy safeguards. The European Commission is now expected to review the executive order and could propose an adequacy decision concerning the level of personal data protection in the U.S. under which personal data could flow freely from the EEA to the U.S.

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. Any failure or perceived failure by us, a company that we acquire, or one of our service providers to comply with laws, regulations, policies, legal or contractual obligations, industry standards or regulatory guidance relating to privacy or data security could result in governmental investigations and enforcement actions, litigation, fines and penalties, exposure

to indemnification obligations or other liabilities, and adverse publicity, all of which could have an adverse effect on our reputation, as well as our business, financial condition, and results of operations.

In addition, states are constantly adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. For example, the CCPA took effect on January 1, 2020 and was later amended by the CPRA. The CPRA went into effect on January 1, 2023. The CCPA, as amended, gives California residents expanded rights, including to access, correct and delete their personal information and to opt-out of certain personal information disclosures, including sales of their personal information and use for cross-context behavioral advertising purposes. It also requires covered companies to provide disclosures to California consumers and includes new audit requirements for higher risk data and opt-out rights for certain uses of sensitive data. The CPRA also created a new California data protection agency authorized to issue substantive regulations which could result in increased privacy and information security enforcement. The agency is in the course of drafting and proposing implementing regulations for the CPRA. The lack of certainty regarding the final state of these regulations could result in significant compliance costs. The amended 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. Although the CCPA currently exempts certain health-related information, including clinical trial data, the amended CCPA may increase our compliance costs and potential liability. Similar state consumer protection laws have passed in other states. Such laws, including those in Colorado, Connecticut, Utah and Virginia, will come into effect this year and have potentially conflicting requirements that would make compliance challenging and present legal risk. In Colorado, the Attorney General's Office has not yet finalized implementing rules. The lack of certainty regarding the final state of these rules could result in significant compliance costs.

With the GDPR, CCPA and other state 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. However, these policies and practices may not be aligned with every applicable legal or regulatory standard immediately, due in part to the rapidly shifting landscape of privacy and data security requirements. A regulatory review or other independent assessment of the privacy program may result in identifying one or more areas of non-compliance. 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. The landscape of laws regulating personal data is constantly evolving, and compliance with these laws requires a flexible privacy framework and substantial resources, and compliance efforts will likely be an increasing and substantial cost in the future.

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

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

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

Risks Related to Our Dependence on Third Parties

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

We have engaged CROs and other third parties to conduct our planned preclinical studies or clinical trials 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 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 or monitoring and managing our data will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised or not made available to us or regulatory authorities, due to the failure to adhere to our clinical protocols, regulatory requirements, contractual obligations or for other reasons, our clinical trials may be extended, delayed or terminated, the strength of our clinical data package may be limited, 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 cGCPs, 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 cGCP 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 clinical trials and post the results of certain completed clinical trials on a government-sponsored database, such as ClinicalTrials.gov, within specified timeframes. This remains our obligation regardless of whether we have contracted any third party to assist and 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 our 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 intend to rely on third parties to manufacture, test, label, package and store clinical and commercial supplies of our product candidates.

We are currently manufacturing, testing, labeling, packaging and storing our product candidates in partnership with CDMOs. We do not own or operate any facilities for product manufacturing, labeling, packaging, storage and distribution or testing. We are dependent on third parties to manufacture, label, package, store, and distribute the clinical and commercial supplies of our current and any future product candidates. We have established a relationship with WuXi Biologics to manufacture certain product candidates for supply under an EUA (if authorized) or BLA or MAA (if approved).

The facilities used by our contract manufacturers and contract testing labs to manufacture and test our product candidates may be inspected by the FDA after we submit our EUA or BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP requirements. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or other regulatory authorities, 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 could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

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

We engaged WuXi Biologics for development and generation of the production cell line starting material 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 Biologics' China-based facilities for clinical supply and commercial supply, if authorized or approved. 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 U.S. Additionally, the biopharmaceutical industry in particular in China is strictly regulated by the Chinese government. Changes to Chinese regulations affecting biopharmaceutical companies are unpredictable and may have a material adverse effect on our partnerships in China, which could have an adverse effect on our business, financial condition, results of operations and prospects.

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

- inability to access sufficient 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;

- a third-party manufacturer may gain knowledge from working with us that could be used to supply one of our competitors with a product that competes with ours; and
- disruptions to operations of our third-party manufacturers or suppliers by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier.

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

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

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

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

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

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

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

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

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, the European Commission or similar regulatory authorities outside the U.S., 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.

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

Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure, armed conflict, or other natural or manmade accidents or incidents that result in the third parties upon whom we depend from being unable to fully utilize their facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event prevented the third parties upon whom we depend from using all or a significant portion of their manufacturing facilities, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. Unforeseen natural or manmade accidents or incidents, such as freezer failure, natural disasters or theft, could also result in loss of cell line starting material. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If the third parties on which we rely are unable to operate their facilities because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain, maintain and enforce patent protection for our 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 U.S. and in other countries with respect to our proprietary technology and product candidates. The risks associated with patent rights generally apply to patent rights that we in-license now or in the future, as well as patent rights that we may own now or in the future. We currently own three issued U.S. patents with claims directed to adintrevimab, ADG10, and methods of use of adintrevimab, alone or in combination with ADG10 (an antibody-based product candidate previously considered for potential use in combination with adintrevimab for the treatment and prevention of COVID-19), respectively. In addition, although we own a number of pending patent applications, we may not be successful in prosecuting our filed patent applications to obtain issuance of additional patents. Accordingly, there can be no assurance that we will be able to obtain patent protection for our product candidates. Our pending Patent Cooperation Treaty ("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. We can provide no assurance that any of our current or future patent applications will result in issued patents or that any issued patents will provide us with any competitive advantage. In addition, the coverage claimed in any such patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Failure to obtain and maintain such issued patents could have a material adverse effect on our ability to develop and commercialize our product candidates.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. We cannot offer any assurances about which of our patent applications will issue, the breadth of any resulting patent or whether any of the issued patents will be found invalid and unenforceable or will be threatened by third parties. We cannot offer any assurances that the breadth of our resulting or granted patents will be sufficient to stop a competitor from developing and commercializing a product, including a biosimilar product, that would be competitive with one or more of our product candidates. There is no assurance that all the potentially relevant prior art relating to our patent and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Since patent applications in the U.S. 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 U.S., 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 U.S. 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 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 or our partner(s) elect not to patent. Whether proprietary information, data and processes were developed internally, through collaboration partnering, or licensed from one or more third parties, we seek to protect them, 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 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 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 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 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 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 U.S. 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 U.S. 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 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-U.S. 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 U.S., 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 U.S. 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, a collaboration agreement and a platform transfer agreement with Adimab, pursuant to which we are obligated to make payments upon achievement of milestone events and royalties. If these agreements are terminated, our business and prospects will be materially and adversely affected.

We are party to the Adimab Assignment Agreement with 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 granted 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.

We are also party to the Adimab Collaboration Agreement with Adimab for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Collaboration Agreement, we will collaborate with Adimab on research programs for a specified number of targets selected by us within a specified time period. Under the Adimab Collaboration Agreement, Adimab granted us a worldwide, non-exclusive license to certain of its platform patents and technology and antibody patents to perform our responsibilities during the Evaluation Term. In addition, we granted Adimab a license to certain of our patents and intellectual property solely to perform Adimab's responsibilities under the research plans. Under the Adimab Collaboration 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 by us, Adimab will assign 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 for the development, manufacture and commercialization of the antibodies for which we have exercised our options and products containing or comprising those antibodies. 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 optioned research program. 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 claiming composition of matter or method of making or using any antibody identified or optimized under the Adimab Collaboration Agreement in such country. In September 2022, we exercised an option under the Adimab Collaboration Agreement.

We are also party to the Adimab Platform Transfer Agreement with Adimab under which we were granted the right under certain intellectual property of Adimab to practice certain elements of Adimab's platform technology, including B-cell cloning using Adimab's proprietary yeast cell lines and other antibody optimization libraries, trade secrets, protocols and software of Adimab, to discover, engineer and optimize antibodies. We do not have access to Adimab's proprietary discovery libraries. We were also granted the right under certain intellectual property of Adimab to research, develop, make, sell and exploit such antibodies and products containing such antibodies. The Adimab platform will be transferred to us in accordance with the terms of the Adimab Platform Transfer Agreement.

During the first four years of the Adimab Platform Transfer Agreement, we owe a fixed annual fee to Adimab, which will allow us to receive material improvements to the platform technology, including materially improved antibody optimization libraries, updates that provide new functionality to the platform, and software upgrades. After such time, we have the option to receive additional material improvements to the platform technology from Adimab, subject to a commercially reasonable fee to be negotiated by the parties. This agreement also contains obligations that require us to make payments to Adimab in the event certain specified development and regulatory milestone events are achieved and royalty payments 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 last valid claim of a program antibody patent for covering the program antibody contained under the Adimab Platform Transfer Agreement in such product in such country.

Our business is reliant upon the intellectual property rights assigned and licensed to us under the Adimab Assignment Agreement, the Adimab Collaboration Agreement and the Adimab Platform Transfer Agreement. If we materially breach the Adimab Assignment Agreement, the Adimab Collaboration Agreement or the Adimab Platform Transfer Agreement, our licenses under the Adimab Assignment Agreement, the Adimab Collaboration Agreement and the Adimab Platform Transfer 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, the Adimab Collaboration Agreement or the Adimab Platform Transfer Agreement is terminated as a result of our breach or otherwise, our business and prospects will be materially and adversely affected.

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

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

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

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to comply with various development, diligence, commercialization and other obligations and meet development timelines, or exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses (for example, under the Adimab Assignment Agreement, we are required to use commercially reasonable efforts to achieve specified development and regulatory milestones for products in certain major markets and to commercialize a product in any country in which we obtain marketing approval);
- we may be required to issue equity securities that would dilute our stockholders' percentage ownership of our company;
- we may be required to assume substantial actual or contingent liabilities;
- we may not be able to control the amount and timing of resources that our strategic collaborators devote to the development or commercialization of our product candidates;
- we may not have the right to control the preparation, filing, prosecution and maintenance of patents and patent applications covering the technology that we license, and we cannot always be certain that these patents and patent applications will be prepared, filed, prosecuted and maintained in a manner consistent with the best interests of our business (for example, we have no rights to control the preparation, filing, prosecution or maintenance of the patents licensed to us under Adimab's antibody discovery and optimization platform technology under the Adimab Assignment Agreement);

- strategic collaborators may select indications or design clinical trials in a way that may be less successful than if we were doing so;
- strategic collaborators may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic collaborators may not pursue further development and commercialization of products resulting from the strategic collaboration arrangement or may elect to discontinue research and development programs;
- strategic collaborators may not commit adequate resources to the marketing and distribution of our product candidates, limiting our potential revenue from these products;
- disputes may arise between us and our strategic collaborators that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic collaborators may experience financial difficulties;
- strategic collaborators may not properly maintain, enforce or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic collaborator's business strategy may adversely affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement;
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors; and
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates.

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

Our license agreements are, and future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the U.S. Furthermore, the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the U.S. 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 (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. 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 U.S. 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 U.S. 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 U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. 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 U.S. and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

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

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

If we initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the U.S., 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 U.S. or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, inter partes review and equivalent proceedings in foreign jurisdictions (for example, opposition proceedings, nullity proceedings or litigation or invalidation trials or invalidation proceedings). Such proceedings could result in revocation of or amendment to our future patents in such a way that they no longer cover our product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patent applications, should they issue as patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates.

Interference or derivation proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions or inventorship (and possibly also ownership) of inventions with respect to our patent applications or resulting patents, or patent applications or resulting patents of third parties. For example, we were notified in October 2020 that a third party claimed that one of its employees should be listed as an inventor on certain of our patent applications claiming

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, we may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any of the foregoing could materially adversely affect our business, results of operations and financial condition.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the U.S. and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. For example, WuXi Biologics has provided only high-level information to us identifying the general nature of the licensed control elements in the expression vector used in the production cell line starting material for adintrevimab manufacturing. Details of the expression technology have not been provided, nor has there been sufficient information provided to enable a freedom-to-operate assessment of the expression technology. We therefore cannot be sure that we have licensed all intellectual property rights that are relevant to or necessary for the commercialization of our product candidates, and a third party may claim that our development or commercialization of our product candidates 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 our product candidates, 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 our product candidates, 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 U.S. or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant third-party patents may negatively impact our ability to develop and market our products.

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to acquire or obtain a license to such intellectual property from these third parties, and we may be unable to do so on commercially reasonable terms or at all. The

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

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

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing, misappropriating or otherwise violating the patents, trademarks, and proprietary rights of third parties. As our product candidates progress toward commercialization, the possibility of a patent infringement claim against us increases. There is a substantial amount of litigation involving patents, trademarks, and other intellectual property rights in the biotechnology and pharmaceutical industries, including infringement lawsuits, interferences, derivation proceedings, post grant reviews, inter partes reviews, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates, and there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates and technologies. Third parties, including our competitors may initiate legal proceedings against us alleging that we are infringing, misappropriating or otherwise violating their patents, trademarks, or other intellectual property rights.

We cannot provide any assurance that our product candidates do not infringe, misappropriate or otherwise violate other parties' patents, trademarks, or other proprietary rights, and competitors or other parties may assert that we infringe, misappropriate or otherwise violate their proprietary rights in any event. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates, including oppositions, interference proceedings, reexaminations, post-grant review, inter partes review, or derivation proceedings before the USPTO in the U.S. 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 VYD222, adintrevimab or any future product candidates. In order to successfully challenge the validity of any U.S. 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 U.S. patent claim, there is no assurance that a court of competent jurisdiction would agree with us and invalidate the claims of any such U.S. 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 U.S. and abroad could uphold the validity of any such patent. Furthermore, because patent applications can take many years to issue and may be confidential for 18 months or more after filing, and because pending patent claims can be revised before issuance, there may be applications now pending which may later result in issued patents that may be infringed by the manufacture, use or sale of our product candidates. Regardless of when filed, we may fail to identify relevant third-party patents or patent applications, or we may incorrectly conclude that a third-party patent is invalid or not infringed by our product candidates or activities. If a patent holder believes that one of our product candidates infringes its patent, the patent holder may sue us even if we have received patent protection for our technology. In addition, third parties may obtain patents in the future and claim that our product candidates or technologies infringe upon these patents. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant drug revenue and against whom our own patent portfolio may thus have no deterrent effect. If a patent infringement suit were threatened or brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the drug or product candidate that is the subject of the actual or threatened suit.

If we are found to infringe, misappropriate or otherwise violate a third party's valid intellectual property rights, we could be required to obtain a license from such third party to continue commercializing our product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. For example, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights

licensed to us. If we fail to obtain a required license, we may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. Alternatively, we may need to redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Under certain circumstances, we could be forced, including by court orders, to cease developing, manufacturing and commercializing our product candidates. In addition, in any such proceeding or litigation, we could be found liable for substantial monetary damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed the patent at issue. We may also be required to indemnify collaborators or contractors against such claims. A finding of infringement, misappropriation or other violation of third-party intellectual property rights could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could harm our business. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar negative impact on our business.

The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation would divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs or in-license needed technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have an adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

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

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our future patents. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

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

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

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

We rely on third parties to manufacture our product candidates, and we collaborate with additional third parties for the development of such product candidates. We therefore must, at times, share trade secrets with them. We may also conduct joint

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

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees, contractors and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Moreover, if confidential information that is licensed or disclosed to us by our partners, collaborators, or others is inadvertently disclosed or subject to a breach or violation, we may be exposed to liability to the owner of that confidential information. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the U.S. are sometimes less willing to protect trade secrets.

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

Filing and prosecuting patent applications and defending patents covering our product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we or our licensors have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or our licensors have patent protection, but enforcement rights are not as strong as those in the U.S. 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. Additionally, unforeseen global events such as the conflict between Russia and Ukraine, and sanctions relating to these events could affect our ability to file, prosecute, and defend patents and patent applications in those jurisdictions.

Further, legal or regulatory action by various stakeholders or governments could potentially result in us not seeking intellectual property protection for or agreeing not to enforce or being restricted from enforcing intellectual property related to our products. Discussions are ongoing at the World Trade Organization (the "WTO") regarding the role of intellectual property in the context of the COVID-19 pandemic response. This includes a proposal that would release WTO members from their obligation under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights to grant and enforce various types of intellectual property protection on health products and technology in relation to the treatment of COVID-19.

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 U.S., 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 U.S. 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. For example, 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. As a result, in response to the COVID-19 pandemic, it is possible that certain countries may take steps to facilitate compulsory licenses that permit the distribution of a COVID-19 therapeutic in those countries. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

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

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the U.S. 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-U.S. 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.

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

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

objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Any of the foregoing events may have a material adverse effect on our business.

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

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

- others may be able to make products that are similar to or otherwise competitive with our product candidates but that are not covered by the claims of any of our patents, should they issue;
- an in-license necessary for the manufacture, use, sale, offer for sale or importation of one or more of our product candidates may be terminated by the licensor;
- we or our collaborators might not have been the first to make the inventions covered by our future issued patents or our pending patent applications;
- we or our collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing, misappropriating or otherwise violating our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or in-license may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or in-license may not provide coverage for all aspects of our product candidates in all countries;
- our competitors might conduct research and development activities in the U.S. 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 U.S. 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, the Physician Payments Sunshine Act and regulations promulgated under such laws. These laws will impact, among other things, our clinical research, proposed sales, marketing and educational programs, and other interactions with healthcare professionals. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term “remuneration” has been broadly interpreted to include anything of value. Although there are a number of statutory exceptions and

regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation;

- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from the federal government, including Medicare, Medicaid and other government payors, that are false or fraudulent or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or to avoid, decrease or conceal an obligation to pay money to the federal government. A claim includes "any request or demand" for money or property presented to the U.S. federal government. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved, and thus non-reimbursable, uses. In addition, the government may assert that a claim, including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and their implementing regulations, also imposes obligations, including mandatory contractual terms, on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as their covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal transparency laws, including the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, medical devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the State Children's Health Insurance Program, with specific exceptions, to report annually to CMS, information related to: (i) payments or other "transfers of value'' made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, and (ii) ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations; state laws that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or that otherwise restrict payments that may be made to healthcare providers; and state and local laws that require the registration of pharmaceutical sales representatives.

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

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will

involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

Even if we obtain regulatory authorization or approval for a product candidate, such products will remain subject to ongoing regulatory oversight, which may result in significant additional expense.

Even if we obtain any regulatory authorization or approval for VYD222, adintrevimab or any future product candidates, they will be subject to ongoing regulatory requirements applicable to manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submission of safety and other post-market information, among other things. Any regulatory approvals that we receive for a product candidate 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, including any limitations on advertising and promotion for a product authorized under an EUA. 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. If our product were granted an EUA, there are conditions the FDA imposes on manufacturers as to permissible form and substance and process for regulatory submission of promotional communications, which conditions are subject to change. If an EUA 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. Furthermore, the FDA may terminate an EUA if safety issues or other concerns about our product, such as loss of neutralizing activity against dominant circulating SARS-CoV-2 variants, arise or if we fail to comply with the conditions of authorization. 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. We need to monitor adverse events resulting from the use of our products candidates, as do the regulatory authorities, and we file periodic reports with the authorities concerning adverse events. The FDA, the competent authorities of the European Union Member States on behalf of the EMA, and the competent authorities of other European countries also periodically inspect our records related to safety reporting. The EMA's Pharmacovigilance Risk Assessment Committee may propose to the Committee for Medicinal Products for Human Use that the marketing authorization holder be required to take specific steps or advise that the existing marketing authorization be varied, suspended or revoked. 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 variation, suspension or withdrawal of marketing authorization, or suspension of manufacturing, or imposition of financial penalties or other enforcement measures.

If we fail to comply with applicable regulatory requirements following approval of a product candidate, 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 VYD222, adintrevimab or any future product candidates and harm our business, financial condition, results of operations and prospects.

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

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. In addition, in order to distribute VYD222, adintrevimab or any future product candidates, if authorized under an EUA, we will need to secure and maintain required state licenses.

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

Authorization and approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory authorization or 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 authorized or approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory authorization or approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required authorizations or approvals, or if regulatory authorizations or 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 U.S. and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the U.S. 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 U.S., 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 U.S. 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 and its implementing regulations as well as efforts to modify them or alter their interpretation or implementation. While the U.S. 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 Act included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and

medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. Additional legislative changes, regulatory changes and judicial challenges related to the ACA remain possible, but the nature and extent of such potential changes or challenges are uncertain at this time. It is unclear how any efforts to modify, or invalidate the ACA, its implementing regulations, or portions thereof, and other reform measures that may be adopted in the future will affect our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013, and due to subsequent legislative amendments to the statute, including the BBA and the Infrastructure Investment and Jobs Act, will remain in effect through 2031. Under current legislation, after a brief pause and reduction to 1% due to COVID-19, the actual reduction in Medicare payments will vary from 2% in 2023 to up to 4% in the final fiscal year of this sequester. The American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single-source and innovator multiple-source drugs, beginning January 1, 2024. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding or otherwise 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 U.S. of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the FDA concurrently released a final rule and guidance in September 2020 providing pathways for states to build and submit importation plans for drugs from Canada. Recently, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 into law. The Inflation Reduction Act of 2022, among other things, amends the longstanding "non-interference" clause under Medicare Part D and now permits the U.S. Department of Health and Human Services to negotiate prescription drug prices with companies, subject to a specified cap, for Medicare units of a specified number of certain brand name drugs or biologics without generic or biosimilar competitors each year, with such prices first set to take effect starting in 2026 for such products reimbursed under Medicare Part D and in 2028 for products reimbursed under Medicare Part B. Congress may continue to consider drug pricing as part of other reform initiatives. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for VYD222, adintrevimab or any other 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 VYD222, adintrevimab or other product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any other products would harm our business, financial condition and results of operations.

Risks Related to Employee Matters and Managing Our Growth

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

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

Recruiting and retaining qualified scientific and clinical personnel and, if we progress the development of our product pipeline toward scaling up for commercialization, manufacturing and sales and marketing personnel, will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees, including our current search for a permanent Chief Financial Officer, may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory authorization or 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.

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 24.3% of the voting power of our outstanding common stock according to a Schedule 13D filed by Adimab on June 24, 2022, which reported ownership as of June 22, 2022. As such, Adimab has the ability to substantially influence us through this ownership position. For example, Adimab, acting together with a small number of our other large stockholders, will be able to control elections of directors, amendments of our organizational documents or approval of any merger, amalgamation, sale of assets or other major corporate transaction. Any transferees or successors of all or a significant portion of Adimab's ownership in us will be able to exert a similar amount of influence over us through their ownership position.

Furthermore, certain of our directors, officers and key employees may have actual or potential conflicts of interest with us because of their positions or affiliations with Adimab or their beneficial ownership of equity in Adimab. Terrance McGuire, a member of the board of directors of Adimab, serves on our board of directors and retains his position and affiliation with Adimab. 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.

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

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

Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, CDMOs, 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 misconduct, including intentional, reckless and/or negligent conduct that violates civil, criminal or administrative laws or regulations, including fraudulent conduct or other illegal activity. Misconduct by these parties could include conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

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

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

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

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

Our stock price may be volatile. Since the IPO and through March 16, 2023, our common stock has traded at prices ranging from $1.42 to $78.82 per share. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the timing, progress and results of our clinical trials 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 VYD222, adintrevimab or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory authorization or approval of our product candidates;
- unanticipated serious safety concerns related to the use of VYD222, adintrevimab or any other product candidate;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;

- announcements by our competitors of new product candidates or technologies, or the results of clinical trials or regulatory decisions;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

The stock market in general, and the Nasdaq Global Market and biotechnology companies in particular, have experienced extreme price and volume fluctuations, including as a result of the COVID-19 pandemic, the ongoing conflict between Russia and Ukraine, increases in inflation rates and disruptions to global supply chain, that have often been unrelated or disproportionate to the prospects of the issuer and which have 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 COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business. For example, on January 31, 2023, a securities class action lawsuit captioned Brill v. Invivyd, Inc., et. al., Case No. 1:23-CV-10254-LTS, was filed against us and certain of our former officers in the U.S. District Court for the District of Massachusetts. The complaint alleges violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the basis of purportedly materially false and misleading statements and omissions concerning ADG20's effectiveness against the Omicron variant of COVID-19. The complaint seeks, among other things, unspecified damages, attorneys' fees, expert fees, and other costs. We believe that we have strong defenses and intend to vigorously defend against this action. However, whether or not the claim is successful, litigation is often expensive and can divert management's attention and resources from other business concerns, which could adversely affect our business. We may be the target of similar litigation in the future.

We previously identified a material weakness in our internal control over financial reporting, we may identify additional material weaknesses in the future that may cause us to fail to meet our reporting obligations or result in material misstatements of our financial statements. If we fail to remediate any such weaknesses, or if we otherwise fail to establish and maintain effective control over financial reporting, our ability to accurately and timely report our financial results could be adversely affected, which may adversely affect our business.

In connection with the preparation of our financial statements for the quarter ended March 31, 2021, we identified a material weakness in our internal control over financial reporting. 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 financial statements will not be prevented or detected on a timely basis.

The material weakness identified related to a lack of 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 financial consolidated financial statements for that quarter. We subsequently designed and implemented controls to remediate the material weakness, including strengthening and formalizing our documentation of policies and further evolving our accounting processes and post-closing review procedures related to the completeness and accuracy of research and development expenses, prepaid expenses, accounts payable and accrued expenses of our contract manufacturing agreements, and our management concluded that we remediated the material weakness as of December 31, 2021.

The process of designing and implementing an effective financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain a financial reporting system that satisfies our reporting obligations. If we are unable to meet the demands that have been placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), and we may be unable to accurately report our financial results, or report them within the timeframes required by law or stock exchange regulations. Failure to comply with the Sarbanes-Oxley Act, when and as applicable, could also potentially subject us to sanctions or investigations by the SEC or other regulatory authorities. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional material weaknesses, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Furthermore, if we cannot provide reliable financial reports or prevent material misstatements due to fraud or error, our business and results of operations could be harmed, and investors could lose confidence in our reported financial information. We also could become subject to investigations by The Nasdaq Stock Market ("Nasdaq"), the SEC or other regulatory authorities. All these possibilities could increase our operating costs and harm our business.

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

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

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

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

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

Additionally, several of our large stockholders, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

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

There are provisions in our amended and restated certificate of incorporation and amended and restated bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by you and other stockholders. For example, our board of directors has 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 also contain other provisions that could have an anti-takeover effect, including:

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

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

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

Our executive officers, directors and current beneficial owners of five percent or more of our common stock and their respective affiliates beneficially own a majority of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these 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," within the meaning of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, as amended (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 the IPO. 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 are$1.235 billion or more 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 take advantage of exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

As a result, our shareholders may not have access to certain information they may deem important. We cannot predict whether investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result of our reliance on these exemptions, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

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

We are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K, and will remain a smaller reporting company until the last day of the fiscal year in which the market value of our common stock held by non-affiliates exceeds $250 million as of the end of that year's second fiscal quarter, or our annual revenues exceeded $100 million during such completed fiscal year and the market value of our common stock held by non-affiliates exceeds $700 million as of the end of that year's second fiscal quarter.

We are therefore entitled to rely on certain reduced disclosure requirements for as long as we remain a smaller reporting company, such as an exemption from providing selected financial data and certain executive compensation information. In addition, for as long as we are a smaller reporting company with less than $100 million in annual revenue, we would be exempt from the requirement to obtain an external audit on the effectiveness of internal control over financial reporting provided in Section 404 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 rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock prices may be more volatile.

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

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

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

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

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

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

- any derivative action or proceeding brought on our behalf;
- any action asserting a breach of fiduciary duty;
- any action asserting a claim against us arising under the Delaware General Corporation Law (the "DGCL"), our amended and restated certificate of incorporation, or our amended and restated bylaws;
- any action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws;
- any action to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and

- any action asserting a claim against us that is governed by the internal-affairs doctrine.

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

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

General Risk Factors

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

As a public company, and particularly after we are no longer an emerging growth company, we have incurred and we will continue to 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 Nasdaq. 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.

We and certain of our former officers have been named as defendants in a pending securities class action lawsuit. We have also received a request from the SEC requesting certain information in connection with an investigation. This lawsuit and investigation, and potential similar or related lawsuits or investigations, could result in substantial damages, divert management's time and attention from our business, and have a material adverse effect on our results of operations. This lawsuit and investigation, and any other lawsuits or investigations to which we are subject, will be costly to defend or comply with and are uncertain in their outcome.

On January 31, 2023, a securities class action lawsuit captioned Brill v. Invivyd, Inc., et. al., Case No. 1:23-CV-10254-LTS, was filed against us and certain of our former officers in the U.S. District Court for the District of Massachusetts. The complaint alleges violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the basis of purportedly materially false and misleading statements and omissions concerning ADG20's effectiveness against the Omicron variant of COVID-19. The complaint seeks, among other things, unspecified damages, attorneys' fees, expert fees, and other costs.

We believe that we have strong defenses, and we intend to vigorously defend against this action. However, whether or not the claim is successful, litigation is often expensive and can divert management's attention and resources from other business concerns, which could adversely affect our business.

We currently are not able to estimate the possible cost to us from this action, as the pending lawsuit is currently at an early stage, and we cannot be certain how long it may take to resolve the pending lawsuit or the possible amount of any damages

that we may be required to pay. If we are ultimately required to pay significant defense costs, damages or settlement amounts, such payments could adversely affect our operations.

Additionally, we received a request from the SEC, dated March 22, 2023, for documents and information concerning, among other matters, our testing and analysis of the efficacy of ADG20 against Omicron and other COVID-19 variants, our public statements regarding the potential use of ADG20 against the Omicron variant, and related communications with investors and the media. While we intend to cooperate fully with this fact-finding inquiry, responding to investigative inquiries is often expensive and can divert management's attention and resources from other business concerns, which could adversely affect our business, regardless of the outcome of the investigation.

We may be the target of similar litigation or investigations in the future. The market price of our common stock has experienced and may continue to experience volatility, and in the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation. Any future litigation or investigation could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business. We maintain liability insurance; however, if any costs or expenses associated with pending lawsuits or any other litigation or investigation exceed our insurance coverage, we may be forced to bear some or all costs and expenses directly, which could adversely affect our business, financial condition, results of operations or stock price.

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, 2022, we had U.S. federal net operating loss ("NOL") carryforwards of $263.7 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, 2022, we had state NOL carryforwards of $103.3 million, which may be available to reduce future taxable income, of which $7.0 million have an indefinite carryforward period while the remaining $96.3 million begin to expire in 2041. As of December 31, 2022, we also had U.S. federal and state research and development tax credit carryforwards of $13.2 million and $3.6 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2041 and 2036 respectively.

Under the Tax Act, as modified by the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"), federal NOLs incurred in taxable years beginning after December 31, 2017 and in future taxable years may carry forward indefinitely, but the deductibility of such federal NOLs incurred in taxable years beginning after December 31, 2020 may be limited. There is variation in how states are responding. In addition, for state income tax purposes, there may be periods during which the use of NOLs is suspended or otherwise limited.

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 IPO, together with private placements and other transactions that have occurred since our inception, may trigger such an ownership change pursuant to Section 382. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced, and may in the future experience, ownership changes as a result of shifts in our stock ownership, some of which may be outside of our control. If an ownership change has occurred or occurs in the future, and our ability to use our NOL carryforwards is materially limited, it would harm our financial condition and results of operations by effectively increasing our future tax obligations.

We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. Beginning in 2022, the Tax Act now eliminates the previously available option to deduct research and development expenditures and requires taxpayers to amortize them over five or fifteen years. Although U.S. Congress considered legislation that would defer the amortization requirement to future periods; the provision has not been repealed or otherwise modified.

Our business activities are subject to the FCPA and similar anti-bribery and anti-corruption laws. We could face liability and other serious consequences for violations.

We are subject to anti-corruption laws and regulations, including 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-U.S. 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-U.S. governments. Additionally, in many other countries, the healthcare providers who

prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

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

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

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

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Since then, the FDA has resumed both domestic and foreign inspections subject to travel restrictions. The FDA continues to adapt to the evolving COVID-19 pandemic, and has increasingly relied on alternative inspectional tools, including product sampling, records requests under Section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act, and remote regulatory assessments, in lieu of or to supplement traditional in-person inspections. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine, terrorism or other geopolitical events. Sanctions imposed by the U.S. and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. Portions of our future clinical trials may be conducted outside of the U.S. 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, higher inflation and interest rates, political disruption or other geopolitical events, including an expansion of the conflict between Russia and Ukraine or instigation of other military conflicts, could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Furthermore, while

we seek to limit our concentration of risk as it relates to cash management by having a separate operating bank account with a U.S. commercial bank for routine disbursements, while maintaining our cash investments with an independent SEC-registered financial advisor, our liquidity, business and financial condition may be materially and adversely affected by unanticipated events such as a bank collapse. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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

Additionally, we lease laboratory and office space in Newton, Massachusetts for research and development purposes. We lease this space under a lease agreement that terminates on November 30, 2024.

We believe that our facilities are sufficient to meet our current needs.

Item 3. Legal Proceedings.

On January 31, 2023, a securities class action lawsuit captioned Brill v. Invivyd, Inc., et. al., Case No. 1:23-CV-10254-LTS, was filed against us and certain of our former officers in the U.S. District Court for the District of Massachusetts. The complaint alleges violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the basis of purportedly materially false and misleading statements and omissions concerning ADG20's effectiveness against the Omicron variant of COVID-19. The complaint seeks, among other things, unspecified damages, attorneys' fees, expert fees, and other costs.

We believe that we have strong defenses and we intend to vigorously defend against this action. The lawsuit is in early stages, and, at this time, no assessment can be made as to the likely outcome or whether the outcome will be material to us.

Additionally, we received a request from the SEC, dated March 22, 2023, for documents and information concerning, among other matters, our testing and analysis of the efficacy of ADG20 against Omicron and other COVID-19 variants, our public statements regarding the potential use of ADG20 against the Omicron variant, and related communications with investors and the media. We intend to cooperate fully with this fact-finding inquiry.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock is listed on the Nasdaq Global Market under the symbol "IVVD".

Holders of Record

As of March 16, 2023, there were 19 holders of record of our common stock. This number does not reflect the beneficial holders of our common stock who hold shares in street name through brokerage accounts or other nominees.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock. We currently anticipate that we will retain all available funds and future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.

Securities Authorized for Issuance under Equity Compensation Plans

Information regarding securities authorized for issuance under equity compensation plans is incorporated by reference into the information in Part III, Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

Other than as previously disclosed on our Current Reports on Form 8-K or Quarterly Reports on Form 10-Q, we did not issue any unregistered equity securities during the twelve months ended December 31, 2022.

Use of Proceeds

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

The initial public offering closed on August 10, 2021. The aggregate net proceeds received by the Company from the initial public offering were approximately $327.5 million, after deducting underwriting discounts and commissions of $24.9 million and offering expenses payable by the Company of $3.4 million. In connection with our initial public offering, no payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates or to our affiliates. Other than the reallocation of proceeds to fund clinical development, manufacturing supply and initial commercialization costs from ADG20 to other product candidates, there has been no material change in the planned use of proceeds from our initial public offering as described in our prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on August 6, 2021.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the quarter ended December 31, 2022.

Item 6. [Reserved]

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

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

Overview

Invivyd, Inc. is a biopharmaceutical company on a mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with COVID-19. Our technology works at the intersection of evolutionary virology, predictive modeling, and antibody engineering, and is designed to identify high-quality, long-lasting antibodies with a high barrier to viral escape. We are generating a robust pipeline of product candidates which could be used in prevention or treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications.

In March 2023, we announced the election of VYD222 to advance into the clinic as a mAb therapeutic option for COVID-19 with a focus on serving vulnerable populations. We aim to leverage evolving COVID-19 regulatory paradigms and maximize efficiency to deliver this much-needed product for immunocompromised individuals and other vulnerable populations.

VYD222 is one of two mAb components of NVD200, a combination mAb product candidate that we previously selected for clinical advancement prior to evolution in the current global COVID-19 regulatory paradigm. We are prioritizing the clinical development of VYD222 instead of NVD200 with the aim of providing patients with a therapeutic option for COVID-19 as quickly and efficiently as possible. VYD222 was engineered from adintrevimab, our investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 3 clinical trials for both the prevention and treatment of COVID-19. The adintrevimab clinical data package has the potential to support accelerated development of VYD222. We continue to plan for a Phase 1 clinical trial start in the first quarter of 2023. Assuming positive Phase 1 data, we anticipate rapidly initiating the Phase 3 pivotal trials that could support regulatory filings globally.

Beyond VYD222, we continue to leverage our expanded lab capabilities and integrated discovery platform to produce additional candidates that will be optimized to stay ahead of the evolving SARS-CoV-2 virus. In addition, we continue to work with regulatory agencies to streamline the development and commercialization plans for novel antibodies to protect immunocompromised and other high-risk populations against the evolving SARS-CoV-2 virus.

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 may become an endemic disease requiring a variety of effective and safe and convenient prevention and treatment options for years to come. We also believe that future pandemics similar to the COVID-19 pandemic are likely because, in many parts of the world, humans live in close proximity to animal species harboring coronaviruses that are capable of infecting humans. We are leveraging our team's collective expertise and capabilities to deliver our COVID-19 antibodies to patients and to discover novel solutions to infectious diseases through internal research and collaborations.

Since our inception, we have devoted substantially all of our resources to organizing and staffing, building an intellectual property portfolio, business planning, conducting research and development, establishing and executing arrangements with third parties for the manufacture of our product candidates and raising capital. We rely heavily on partnerships, external consultants and CROs to conduct our discovery, non-clinical, preclinical and clinical activities. Additionally, we are currently dependent on WuXi Biologics, a CDMO, for the development and manufacture of our product candidates for clinical and commercial use. Further, in 2022, we secured dedicated laboratory space and expanded our research team in order to enable internal discovery and development of our mAb candidates, while continuing to leverage our existing partnership with Adimab LLC, or Adimab. We are focused on antibody discovery and use of Adimab's platform technology while building our internal capabilities. We expect to continue to rely on third parties for clinical trials and the manufacture and testing of our product candidates, as well as to perform ongoing research and development and other services on our behalf.

Since our inception, we have financed our operations with net proceeds of $464.7 million from sales of our preferred stock, and most recently, with net proceeds from our IPO. In August 2021, we completed our IPO, pursuant to which we issued and sold 20,930,000 shares of our common stock, including 2,730,000 shares of common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds from our IPO of $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us. To date, we have not generated any revenue from any sources, including product sales or government supply contracts. 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 a net loss of $241.3 million for the year ended December 31, 2022. As of December 31, 2022, we had an accumulated deficit of $533.4 million. We expect to continue to incur significant expenses and recognize losses in the foreseeable future as we expand and progress our research and development activities, as well as the associated manufacturing activities and commercialization efforts. In addition, our losses from operations may fluctuate significantly from period to period depending on the timing of our clinical trials and our expenditures on other research and development activities, including any associated manufacturing activities, and potential commercialization efforts. Our expenses could increase substantially in connection with our ongoing activities, as we:

- initiate and conduct clinical trials of VYD222 or any other product candidate;
- develop 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, including development and screening of additional antibodies;
- seek regulatory authorization or 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 discovery technologies;
- further develop and validate our commercial-scale cGMP manufacturing process for VYD222;
- manufacture material under cGMP at our contracted manufacturing facilities for clinical trials and potential EUA, regulatory approval and commercial sales;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory approval or EUA;
- hire and retain additional personnel, including research, clinical, development, manufacturing, quality control, quality assurance, regulatory and scientific personnel;
- add operational, financial, corporate development, management information systems and administrative personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur additional legal, accounting and other expenses in operating as a public company.

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

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant product revenue, 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, strategic alliances and licensing arrangements. 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 and emergence of adintrevimab susceptible SARS-CoV-2 VoCs, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. We may never obtain regulatory approval for any of our product candidates. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities of $372.0 million as of December 31, 2022, will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources."

Impact of COVID-19 on Our Operations

The full impact of the COVID-19 pandemic and the disease continues to evolve and change as of the date of this Annual Report on Form 10-K, and such impact will directly affect the potential commercial prospects of VYD222 and other product candidates for the prevention and treatment of COVID-19. The severity of the COVID-19 pandemic, the evolution of the disease and the continued emergence of VoCs, the availability, administration and acceptance of vaccines, mAbs, antiviral agents and other therapeutic modalities, vaccine mandates by employers and/or local or national governments, 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.

Similarly, it is not possible to determine the scale and rate of economic recovery from the pandemic, supply chain disruptions, and labor availability and costs, or the impact of other indirect factors that may be attributable to the pandemic. The ultimate extent of the impact of the COVID-19 pandemic on our business, financial condition, operations and product development timelines and plans remains uncertain and will depend on future developments, including the duration and spread of outbreaks and the continued emergence of variants, its impact on our clinical trial design and enrollment, trial sites, 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 experienced some delays and disruptions in our development activities as a result of the COVID-19 pandemic. Some of our CROs, CDMOs and other service providers also continue to be impacted. We will continue to monitor developments as we address the disruptions, delays and uncertainties relating to the COVID-19 pandemic. If the financial markets and/or the overall economy are impacted for an extended period, our results and operations may be materially adversely affected and may affect our ability to raise capital.

Components of Our Results of Operations

Revenue

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

Research and Development Expenses

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

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

Such costs consist of:

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

- laboratory-related expenses, which include equipment, laboratory supplies, rent expense, depreciation expense, and other operating costs;
- 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 antibodies against COVID-19. 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. Our research and development expenses could increase substantially in the near term as we advance VYD222 through clinical development, pursue EUA or regulatory approval of our product candidates, 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 IND applications with the FDA or comparable foreign applications that allow commencement of our planned clinical trials or future clinical trials for our product candidates;
- sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials, manufacture the product candidates and complete associated regulatory activities;
- our ability to establish and maintain agreements with third-party manufacturers for clinical supply for our clinical trials and successfully develop, obtain regulatory approval or EUA for our product candidates;
- successful enrollment and timely completion of clinical trials, including our ability to generate positive data from any such clinical trials;
- the costs associated with the development of any additional development programs and product candidates we identify in-house or acquire through collaborations;
- the prevalence, nature and severity of adverse events experienced with any 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 cGCPs, 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; 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 emergency situations, such as a pandemic, and with a declaration of a public health emergency by the U.S. HHS, the FDA has the authority to issue an EUA. While the Biden Administration announced that it would allow the COVID-19 public health emergency declared by HHS under the Public Health Service Act to expire on May 11, 2023, this does not impact the FDA's ability to authorize COVID-19 drugs and biological products for emergency use. The FDA may continue to issue new EUAs going forward when criteria for issuance are met. Such ability arises from the EUA declaration and determination issued pursuant to the FDCA, which remain in effect unless or until the HHS Secretary terminates such declaration and determination, at which point EUAs based on such declaration would cease to be in effect and the FDA may no longer issue EUAs for products covered by such declaration. There can be no assurance that the public health emergency in the U.S. declared under the FDCA will continue to be in place for an extended period of time, that any of our product candidates will be granted an EUA by the FDA, if we apply for such an authorization, or that we would be able to maintain an EUA, if received, for an extended period of time.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development ("IPR&D") expenses consist primarily of the upfront costs we incurred in July 2020, as well as any costs of contingent milestone payments we incurred in subsequent periods, to acquire rights to Adimab's antibodies relating to COVID-19 and SARS and related intellectual property and a license to certain of Adimab's platform patents and technology (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 it is deemed probable that we will make contingent milestone payments to Adimab under the terms of the agreement by which we acquired the IPR&D assets.

Selling, General and Administrative Expenses

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

Our selling, general and administrative expenses could increase 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 could incur additional commercialization expenses prior to any regulatory approval or EUA of our product candidates as we continue to expand our commercial function to support potential future product launches. We also anticipate that we will continue to 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.

In June 2022, and subsequently amended in September 2022, we entered into a noncancelable agreement for dedicated laboratory and office space in Newton, MA for research and development purposes. Through December 31, 2022, we have operated as a virtual company and maintained a corporate headquarters for general and administrative purposes only. Therefore, we did not incur material operating expenses for the rent, maintenance and insurance of facilities, or for depreciation of fixed assets.

Warrant Expense

In November 2022, we entered into the PHP MSA with PHP, pursuant to which PHP agreed to provide services and create deliverables for us as agreed between us and PHP and set forth in one or more work orders under such agreement. As

compensation for the services and deliverables, we issued the PHP Warrant to PHP. The aggregate grant date fair value of the PHP Warrant was recognized as warrant expense on the grant date. On the effective date of the PHP MSA, we and PHP entered into the first work order under the PHP MSA, pursuant to which PHP agreed to advise and us regarding clinical development and regulatory matters with respect to our product candidates. Clive Meanwell, M.D. and Tamsin Berry, members of our board of directors, are Managing Partner and Partner of PHP, respectively.

As a result, warrant expense consists of non-cash expense related to the issuance of the PHP Warrant.

Other Income (Expense), Net

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

Income Taxes

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

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Operating expenses:		
Research and development	$ 179,214	$ 182,891
Acquired in-process research and development	4,400	7,500
Selling, general and administrative	47,044	36,517
Warrant expense	17,373	—
Total operating expenses	248,031	226,908
Loss from operations	(248,031)	(226,908)
Other income (expense):		
Other income (expense), net	6,714	118
Total other income (expense), net	6,714	118
Net loss	$ (241,317)	$ (226,790)

Research and Development Expenses

	Year Ended December 31,	
(in thousands)	**2022**	**2021**
Direct, external research and development expenses by program:		
Adintrevimab	$ 106,024	$ 136,470
NVD200[(1)]	19,665	—
Unallocated research and development expenses:		
Personnel related (including stock-based compensation)	37,181	23,470
External discovery-related and other costs[(2)]	16,344	22,951
Total research and development expenses	$ 179,214	$ 182,891

[(1)] NVD200, a combination product that we previously selected for clinical advancement, includes costs associated with VYD222 and other mAbs evaluated for potential advancement prior to making the decision to prioritize VYD222 instead of NVD200.

[(2)] In 2022, we reclassified costs associated with ADG10, an antibody-based product candidate previously considered for potential use in combination with adintrevimab for the treatment and prevention of COVID-19, into external discovery-related

and other costs. We have discontinued development of ADG10 due to its less favorable neutralization profile compared to adintrevimab.

Research and development expenses were $179.2 million for the year ended December 31, 2022, compared to $182.9 million for the year ended December 31, 2021. The $3.7 million decrease in research and development expenses was primarily due to the following:

- The decrease in direct costs related to our adintrevimab program of $30.4 million was primarily due to a decrease in our contract research expenses. Contract research expenses decreased $27.2 million primarily related to lower costs due to a pause in enrollment and closing of clinical trials in January and November 2022, respectively. Contract manufacturing expenses increased primarily related to the production of materials for use in our clinical trials and nonclinical studies and production of commercial supply for a potential EUA for the adintrevimab program procured from WuXi Biologics, our sole-source supplier of drug substance and drug product. The increase in contract manufacturing expenses was offset by the recognition of the eight-figure WuXi Biologics credit, for a net decrease of $0.3 million. In addition, other external and non-clinical expenses decreased by $3.0 million.
- The increase in direct expenses related to NVD200 is due to the nomination of our NVD200 product candidate in 2022 to proceed to IND-enabling activities. The costs primarily related to contract manufacturing expenses for the manufacture of materials for use in our clinical trials and non-clinical studies.
- Personnel-related costs, including salaries, bonuses, benefits and other compensation-related costs were $24.4 million and stock-based compensation expense was $12.8 million for the year ended December 31, 2022, compared to personnel-related costs of $16.9 million and stock-based compensation expense of $6.6 million for the year ended December 31, 2021. The increase in personnel-related costs of $13.7 million was primarily due to the hiring of additional individuals to support the development of our product candidates, including an increase in stock-based compensation expense of $6.2 million.
- The decrease in external discovery-related and other costs of $6.6 million was primarily due to a decrease of $10.9 million of direct costs related to ADG10 during the year ended December 31, 2021, for which there were no comparable costs during the year ended December 31, 2022. This decrease was offset by an increase in external discovery-related and other costs of $4.3 million primarily due to an increase of $2.6 million related to the quarterly fee under the Adimab Collaboration Agreement, which commenced during the three months ended September 30, 2021, an increase of $0.7 million related to services performed by Adimab on our behalf under the Adimab Assignment Agreement and the Adimab Collaboration Agreement, an increase of $1.7 million related to information technology costs, software expenditures, and insurance costs, an increase of $1.0 million in laboratory-related expenses, which include equipment, laboratory supplies, rent expense and other operating costs, offset by a decrease of $1.7 million in other external discovery-related and other costs.

Acquired In-Process Research and Development Expenses

Acquired IPR&D expenses of $4.4 million for the year ended December 31, 2022 consisted of $3.0 million incurred related to our upfront consideration payable for the rights assigned pursuant to the Adimab Platform Transfer Agreement, $1.0 million incurred related to an option exercise pursuant to the Adimab Collaboration Agreement and $0.4 million incurred related to discovery delivery fees pursuant to the Adimab Collaboration Agreement.

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

Selling, General and Administrative Expenses

(in thousands)	Year Ended December 31, 2022	2021
Personnel related (including stock-based compensation)	$ 21,153	$ 19,540
Professional and consultant fees	23,884	15,563
Other	2,007	1,414
Total selling, general and administrative expenses	$ 47,044	$ 36,517

Selling, general and administrative expenses were $47.0 million for the year ended December 31, 2022, compared to $36.5 million for the year ended December 31, 2021. The $10.5 million increase in selling, general and administrative expenses was primarily due to the following:

- Personnel-related costs, including salaries, bonuses, benefits and other compensation-related costs were $12.4 million and stock-based compensation expense was $8.8 million for the year ended December 31, 2022, compared to personnel-related costs of $8.3 million and stock-based compensation expense of $11.2 million for the year ended December 31, 2021. The increase in personnel-related costs of $1.6 million was primarily due to the hiring of additional individuals to support our operations as we began operating as a public company, partially offset by the reversal of stock-based compensation expense related to the forfeiture of stock options in conjunction with the resignation of our former Chief Executive Officer and President.
- The increase in professional services and consultant fees of $8.3 million was primarily due to costs incurred as we began operating as a public company, including expenses related to corporate governance matters, director and officer insurance premiums, audit and other fees.
- Other costs remained relatively consistent between periods.

Warrant Expense

Warrant expense for the year ended December 31, 2022 was $17.4 million, consisting of warrant expense recognized as compensation for the services performed in conjunction with the PHP MSA executed in November 2022.

No warrant expense was recognized for the year ended December 31, 2021.

Other Income (Expense), Net

Other income (expense), net for the year ended December 31, 2022 was $6.7 million, consisting primarily of $3.9 million of interest earned on our invested cash balances and $2.8 million of net accretion of discounts related to our marketable securities.

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

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 or government supply contracts, and have incurred significant operating losses and negative cash flows from operations. We expect to incur substantial expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. To date, we have financed our operations with net proceeds of $464.7 million from sales of our preferred stock, and with aggregate net proceeds from our IPO in August 2021 of $327.5 million.

As of December 31, 2022, we had cash, cash equivalents and marketable securities of $372.0 million.

Cash Flows

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

(in thousands)	Year Ended December 31, 2022	2021
Net cash used in operating activities	$ (219,987)	$ (184,736)
Net cash used in investing activities	(230,667)	(50,711)
Net cash provided by financing activities	506	662,683
Net (decrease) increase in cash and cash equivalents	$ (450,148)	$ 427,236

Operating Activities

During the year ended December 31, 2022, operating activities used $220.0 million of cash, primarily due to our net loss of $241.3 million, partially offset by non-cash charges of $37.5 million. Net cash provided by changes in our operating assets and liabilities consisted of a $34.9 million decrease in accrued expenses, a $20.4 million decrease in prepaid expenses and other current assets, a $4.3 million decrease in accounts payable, and a $3.1 million decrease in other non-current assets. The decrease in accounts payable and accrued expenses was primarily due to the timing of vendor invoicing and payments. The decrease in prepaids expenses and other current assets and in other non-current assets was primarily due to our utilization of WuXi Biologics manufacturing deposits.

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

Investing Activities

During the year ended December 31, 2022, net cash used in investing activities was $230.7 million, primarily related to purchases of marketable securities of $298.0 million and purchases of property and equipment of $1.7 million, offset by maturities of marketable securities of $69.0 million.

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

Financing Activities

During the year ended December 31, 2022, net cash provided by financing activities was $0.5 million, primarily related to $0.2 million from exercises of stock options and $0.3 million from issuances of common stock under the employee stock purchase plan.

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

Funding Requirements

Our expenses could increase in connection with our ongoing activities, particularly as we advance the non-clinical and preclinical studies and the clinical trials of our product candidates, including any associated manufacturing activities, and potential commercialization efforts. 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 VYD222 and our other product candidates;
- the scope, progress, results and costs of discovery, non-clinical studies, preclinical development, laboratory testing and clinical trials for our 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 of manufacturing and validation activities associated with our current product candidates with the development and manufacturing of 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 for any product candidates for which we may obtain regulatory approval or EUA;
- the timing and costs of securing sufficient capacity for clinical and commercial supply of our current and potential future 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 U.S. and other jurisdictions, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where approval is obtained;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- the continuation of our existing licensing and collaboration arrangements and entry into new collaborations and licensing arrangements, if at all;
- the need and ability to hire additional research, clinical, development, scientific and manufacturing personnel;
- the costs we incur in maintaining business operations;
- the need to implement additional internal systems and infrastructure;
- the effect of competing technological, product and market developments;
- the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs of operating as a public company; and
- the progression of the COVID-19 pandemic and emergence of potential outbreaks of other coronaviruses, including the impact of any business interruptions to our operations or to those of our contract manufacturers, suppliers or other vendors resulting from the COVID-19 pandemic or other similar public health crises.

We believe that our cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Until such time, if ever, as we can generate significant product revenue, we expect to finance our operations through a combination of equity offerings, government or private-party grants, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences and anti-dilution protections that adversely affect your rights as a common stockholder. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions,

such as incurring debt, making acquisitions or capital expenditures or declaring dividends, which could adversely constrain our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute your ownership interest. If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or through other sources, when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

Clinical and Manufacturing Commitments

In July 2020, we entered into a Clinical Master Services Agreement with WuXi Biologics (the "Clinical Master Services Agreement"). The Clinical Master Services Agreement outlines the terms and conditions under which WuXi Biologics coordinates biologics development and clinical manufacturing services for us.

In December 2020, we entered into a Commercial Manufacturing Services Agreement with WuXi Biologics, which was amended and restated in August 2021 (as amended and restated, the "Commercial Manufacturing Agreement"). The Commercial Manufacturing Agreement outlines the terms and conditions under which WuXi Biologics manufactures drug substance and drug product for commercial use.

We committed to minimum noncancelable purchase obligations related to batches of adintrevimab drug substance and certain services with respect to the product requirements for 2022 and 2023 and batches of adintrevimab drug product and certain services with respect to the product requirements for 2022, the payments for which will extend into 2023.

In April 2022, the total volume of contractually binding drug substance and drug product batches to be manufactured under the Commercial Manufacturing Agreement was reduced to $51.6 million, a decrease of $107.8 million from the previous commitment of minimum non-cancelable purchase obligations of $159.4 million. In addition, WuXi Biologics agreed to provide the Company with a credit in the low eight-figures to offset future services rendered by WuXi Biologics.

In July 2022, we provided notice to WuXi Biologics to cancel the contractually binding adintrevimab drug product batches.

In November 2022, WuXi Biologics reassigned the remaining contractually binding adintrevimab drug substance batches under the Commercial Manufacturing Agreement to contractually binding NVD200 drug substance batches under its Clinical Master Services Agreement. As of December 31, 2022, the total remaining cost of contractually binding NVD200 drug substance batches to be manufactured under the Clinical Master Services Agreement is $18.1 million, which is expected to be incurred and paid in 2023.

In March 2023, the remaining contractually binding batches were repurposed, and the related services now relate to manufacturing of VYD222.

During the year ended December 31, 2022, the majority of the low eight-figure credit was applied to WuXi Biologics services as a reduction of research and development expenses and a reduction of accounts payable and accrued expenses. The remaining portion of the credit is expected to be utilized during the first quarter of 2023.

Operating Lease Commitments

In September 2021, we entered into a five-year noncancelable facilities lease agreement for approximately 9,600 square feet of office space in Waltham, Massachusetts. The monthly rental payments under the lease, which include base rent charges of $0.4 million per year, are subject to periodic rent increases through September 2026. In addition to base rent, monthly rental payments include our proportionate share of operating expenses. The lease terms provide for one five-year extension term with base rent calculated on the then-market rate.

In June 2022, we entered into a two-year noncancelable agreement for dedicated laboratory and office space in Newton, Massachusetts (the "Newton, MA Lease"). The monthly rental payments under the agreement include base rent charges of $0.7 million per year. The agreement terms provide for a month-to-month extension after completion of the initial two-year term with base rent calculated on the then-market rate with three months' prior notice.

In September 2022, we amended the Newton, MA Lease. We entered into a separate two-year noncancelable agreement for new dedicated laboratory and office space on the same campus as the Newton, MA Lease. We took occupancy of the new dedicated laboratory and office space in December 2022. The monthly rental payments under the amended agreement include base rent charges of $1.3 million per year. The agreement terms provide for a month-to-month extension, after completion of the initial two-year term extending through November 2024, with base rent calculated on the then-market rate with three months' prior notice.

Future minimum lease payments under the noncancelable leases as of December 31, 2022 were as follows (in thousands):

Year Ending December 31,	Operating Lease
2023	$ 1,731
2024	1,521
2025	430
2026	328
Total lease payments	4,010
Present value adjustment	(286)
Present value of operating lease liability	$ 3,724

Other Commitments

Under a separate cell line license agreement with WuXi Biologics, as of December 31, 2020, as amended on February 2, 2023, we were obligated to pay a license fee of $0.2 million to WuXi Biologics, which was an accrued expense as of December 31, 2020 and paid during the year ended December 31, 2021. Under the agreement, we are obligated to pay royalties of less than 1.0% to WuXi Biologics based on our net sales of any products covered by the license. However, if we use WuXi Biologics to manufacture all of our commercial supplies, no royalties would be owed by us to WuXi Biologics for net sales of licensed products. We have an option to buy out our royalty obligations by making a one-time payment in the low eight-figures to WuXi Biologics. The amount and timing of such royalty payments are not known. For additional information, see Note 7 to our annual consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

In July 2020, we entered into the Adimab Assignment Agreement with Adimab, with respect to discovery and optimization of coronavirus-specific antibodies, including COVID-19 and SARS. Under the Adimab Assignment Agreement, we are obligated to pay Adimab up to $16.5 million upon the achievement of specified development and regulatory milestones for the first product licensed under the agreement that achieves specified development and regulatory events and up to $8.1 million upon the achievement of specified development and regulatory milestones for the second product licensed under the agreement that achieves such development and regulatory events. In February 2021, we achieved the first specified milestone under the agreement upon dosing of the first patient in a Phase 1 global clinical trial evaluating adintrevimab, which obligated us to make a $1.0 million payment to Adimab. We made the payment in March 2021. In April 2021, we achieved the second specified milestone under the agreement upon dosing of the first patient in a Phase 2 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated us to make a $2.5 million payment to Adimab. We made the payment in June 2021. In August 2021, we achieved the third specified milestone under the agreement upon dosing of the first patient in a Phase 3 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated us to make a $4.0 million milestone payment to Adimab. The next potential milestone under the Adimab Assignment Agreement is a low six-digit dollar milestone related to dosing of the first subject in a Phase 1 trial. 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. The amount and timing of such milestone and royalty payments are not known. For additional information, see Note 7 to our annual consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

In May 2021, as amended in November 2022, we entered into the Adimab Collaboration Agreement with Adimab for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Collaboration Agreement, we and Adimab will collaborate on research programs for a specified number of targets selected by us within a specified time period. Under the agreement, we are obligated to pay Adimab a quarterly fee of $1.3 million, in exchange for Adimab and its affiliates agreeing not to assist or direct certain third parties to discover or optimize antibodies that are intended to bind to coronaviruses or influenza viruses, which obligation may be cancelled at our option at any time. For each agreed upon research program that is commenced, we are obligated to pay Adimab quarterly for its services performed during a given research program at a specified full-time equivalent rate; a discovery delivery fee of $0.2 million; and an optimization completion fee of $0.2 million. For each option exercised by us to commercialize a specific research program, we are obligated to pay Adimab an exercise fee of $1.0 million. In September 2022, we exercised an option under the Adimab Collaboration Agreement, which obligated us to make a $1.0 million payment to Adimab. 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. The next potential milestone under the Adimab Collaboration Agreement is a low single-digit million dollar milestone related to dosing of the first subject in a Phase 1 trial. 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. The amount and timing of such milestone and royalty payments are not known. For additional information, see Note 7 to our annual consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

In September 2022, we entered into the Adimab Platform Transfer Agreement with Adimab, under which we were granted the right under certain intellectual property of Adimab to practice certain elements of Adimab's platform technology, including B-cell cloning using Adimab's proprietary yeast cell lines and other antibody optimization libraries, trade secrets, protocols and software of Adimab, to discover, engineer and optimize antibodies. We do not have access to Adimab's proprietary discovery libraries. We were also granted the right under certain intellectual property of Adimab to research, develop, make, sell and exploit such antibodies and products containing such antibodies. Under the agreement, we are obligated to pay Adimab an annual fee of single digit millions through June 2027. Beginning in July 2027 and ending in June 2042, unless terminated earlier, we have the option to receive additional material improvements to the platform technology from Adimab, subject to a commercially reasonable fee to be negotiated by the parties. We are also obligated to pay Adimab up to $9.5 million upon the achievement of specified development and regulatory milestones for each product under the Adimab Platform Transfer Agreement that achieves such milestones. The next potential milestone under the Adimab Platform Transfer Agreement is a mid-six-digit dollar milestone related to the start of IND-enabling toxicology studies. In addition, we are obligated to pay Adimab royalties of a low single-digit percentage based on net sales of products containing an antibody discovered, engineered or optimized using Adimab's platform technology, once commercialized. The amount and timing of such royalty payments are not known. For additional information, see Note 7 to our annual consolidated financial statements appearing at the end of this Annual Report on Form 10-K.

In November 2022, we entered into the PHP MSA. Concurrently with the PHP MSA, we entered into the first work order with PHP under the PHP MSA, pursuant to which PHP agreed to advise and counsel us regarding clinical development and regulatory matters with respect to our product candidates. The PHP Work Order is effective for six months from November 2022 and may be extended by written agreement of us and PHP. As compensation for the services and deliverables under the PHP Work Order, we are obligated to pay PHP a cash fee of $0.5 million per month during the term of the PHP Work Order for an aggregate fee of $3.0 million. In the event that (i) we terminate the PHP Work Order for any reason other than material breach by PHP or (ii) PHP terminates the PHP Work Order due to material breach by us, in each case, pursuant to the terms of the PHP MSA, we would be required to pay PHP the balance of the Aggregate Fee as of the date the PHP Work Order is terminated. The cash fee is subject to change if the parties extend the term of the PHP Work Order in accordance with the terms thereof.

We enter into other contracts in the normal course of business with CROs, CMOs 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.

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 U.S. ("GAAP"). The preparation of consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience, known trends and events, and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and recorded amounts of expenses that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Accrued Research and Development Expenses

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

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

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

Stock-Based Compensation

We grant stock-based awards to employees, directors and non-employees in the form of stock options to purchase shares of our common stock. We measure stock options with service-based vesting granted to employees, directors and non-employees based on the fair value on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model uses as inputs the fair value of our common stock and assumptions we make for the volatility of our common stock, the expected term of our stock options, the risk-free interest rate for a period that approximates the expected term of our stock options, and our expected dividend yield. After the initial public offering, the fair value of our common stock is based on the quoted market price of our common stock. Due to the proximity to the IPO, we continue to lack company-specific historical and implied volatility information. Therefore, we estimate our expected stock volatility based on the historical volatility of a publicly traded set of peer companies and we expect to continue to do so until such time that we have adequate historical data regarding the volatility of our own traded stock price. We have issued awards with only service-based vesting conditions through December 31, 2022. 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.

Warrant Expense

We have granted stock-based awards consisting of warrants to a non-employee service provider. We estimate the fair value of warrants granted using the Geometric Brownian Motion model. The Geometric Brownian Motion model requires certain subjective inputs and assumptions, including the fair value of our common stock, the expected term, risk-free interest rates, expected stock price volatility, and expected dividend yield of our common stock. The fair value of warrants is recognized as warrant expense on a straight-line basis over the requisite service period. We account for forfeitures as they occur.

These assumptions used in the Geometric Brownian Motion model, other than the fair value of our common stock, are estimated as follows:

- *Expected term.* We estimated the expected term based on the full contractual time to expiration.
- *Risk-free interest rate.* The risk-free interest rate was based on the term matched U.S. Treasury yield curve in effect at the time of grant.
- *Expected volatility.* We estimated the volatility of our common stock on the date of grant based on the re-levered 3rd quartile asset volatility of the comparable publicly-traded companies.
- *Expected dividend yield.* Expected dividend yield is zero, as we have not paid and do not anticipate paying dividends on our common stock.

We continue to use judgment in evaluating the expected volatility and expected term utilized in our stock-based compensation expense calculation on a prospective basis. As we continue to accumulate additional data related to our common stock, we may refine our estimates of expected volatility and expected term, which could materially impact our future stock-based compensation expense.

Recently Issued Accounting Pronouncements

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

Emerging Growth Company Status

We are an “emerging growth company,” as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering. However, if certain events occur prior to the end of such five-year period, including if we become a “large accelerated filer,” our annual gross revenues exceed $1.235 billion or we issue more than $1.0 billion of non-convertible debt in the previous three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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.

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

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

Item 8. Financial Statements and Supplementary Data.

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

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Based on that evaluation of our disclosure controls and procedures as of December 31, 2022, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures as of such date were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act). Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2022, our internal control over financial reporting was effective. As an "emerging growth company" as defined in the JOBS Act and a non-accelerated filer, we are not required to comply with the auditor attestation requirement of Section 404 of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this Item 10 (other than as set forth below) will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates (our "Proxy Statement"), which information is incorporated herein by reference.

We have adopted a Code of Business Ethics and Conduct within the meaning of Item 406(b) of Regulation S-K. This Code of Business Ethics and Conduct applies to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and is posted in the "Corporate Governance" sub-section of the "Investors & Media" section (https://investors.invivyd.com/) of our corporate website (https://invivyd.com/). We intend to disclose on our website any amendments to, or waivers from, the Code of Business Ethics and Conduct that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our Proxy Statement, which information is incorporated herein by reference.

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

The information required by this Item 12 will be included in our Proxy Statement, which information is incorporated herein by reference.

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

The information required by this Item 13 will be included in our Proxy Statement, which information is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in our Proxy Statement, which information is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

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

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

(a)(3) Exhibits:

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on August 10, 2021).
3.2	Certificate of Amendment to the Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on September 13, 2022).
3.3	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on September 13, 2022).
3.4	Delaware Certificate of Change of Registered Agent (incorporated by reference to Exhibit 3.3 of the Registrant's Registration Statement on Form S-3 (File No. 333-267643), filed with the Securities and Exchange Commission on September 28, 2022).
4.1	Second Amended and Restated Investors' Rights Agreement by and among the Registrant and certain of its stockholders, dated April 16, 2021 (incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
4.2*	Description of the Registrant's Common Stock.
4.3*	Common Stock Purchase Warrant.
10.1+	2020 Equity Incentive Plan and Forms of Stock Option Agreement, Notice of Stock Option Grant and Notice of Exercise (incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on November 10, 2022).
10.2+	2021 Equity Incentive Plan and Forms of Option Grant Notice and Agreement, Exercise Notice, Early Exercise Notice and Restricted Stock Award Notice (incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on November 10, 2022).
10.3+	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.6 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on November 10, 2022).
10.4*+	Form of Indemnification Agreement with Executive Officers and Directors
10.5+	Employment Agreement by and between the Registrant and Tillman U. Gerngross, dated August 5, 2021 (incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on September 20, 2021).
10.6+	Amended and Restated Employment Agreement by and between the Registrant and Rebecca Dabora, dated August 5, 2021 (incorporated by reference to Exhibit 10.7 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on September 20, 2021).
10.7+	Amended and Restated Employment Agreement, by and between the Registrant and Jane Pritchett Henderson, dated August 5, 2021 (incorporated by reference to Exhibit 99.1 of the Registrant's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 21, 2022).
10.8+	First Amendment to the Amended and Restated Employment Agreement of Jane Henderson by and between the Registrant and Jane Pritchett Henderson, dated March 18, 2022 (incorporated by reference to Exhibit 10.12 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 31, 2022).
10.9+	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.5 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 31, 2022).

10.10+	Employment Agreement by and between the Registrant and Jill Andersen, dated September 24, 2021 (incorporated by reference to Exhibit 10.11 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 31, 2022).
10.11†#	Assignment and License Agreement by and between the Registrant and Adimab, LLC, dated July 8, 2020 (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
10.12†#	Collaboration Agreement by and between the Registrant and Adimab, LLC, dated May 21, 2021 (incorporated by reference to Exhibit 10.6 of the Registrant's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
10.13*†	Amendment Number One to the Collaboration Agreement by and between the Registrant and Adimab, LLC, November 18, 2022.
10.14†#	Amended and Restated Commercial Manufacturing Services Agreement by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated August 12, 2021 (incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on November 15, 2021).
10.15†#	Cell Line License Agreement by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated December 2, 2020 (incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (File No. 333-257975), filed with the Securities and Exchange Commission on July 16, 2021).
10.16*†	Amendment No. 1 to the Cell Line License Agreement by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated February 2, 2023.
10.17*†	Clinical Master Services Agreement by between the Registrant and WuXi Biologics (Hong Kong) Limited, dated July 21, 2020.
10.18+	Employment Agreement by and between the Registrant and David Hering, dated July 5, 2022 (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on July 5, 2022).
10.19+	Consulting Services Agreement, effective as of October 13, 2022, by and between the Registrant and Fred Driscoll (incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on October 13, 2022).
10.20*	Master Services Agreement by and between the Registrant and Population Health Partners, L.P., dated November 15, 2022.
10.21*†	Work Order by and between the Registrant and Population Health Partners, L.P., dated November 15, 2022.
10.22+	Employment Agreement by and between the Registrant and Jeremy Gowler, dated September 17, 2022 (incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on December 6, 2022).
10.23*+#	Separation Agreement by and between the Registrant and Jane Pritchett Henderson, dated November 11, 2022.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*^	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*^	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104*	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

+ Indicates management contract or compensatory plan.

† Certain portions of this exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Certain schedules to this agreement have been omitted in accordance with Item 601(a)(5) of Regulation S-K. A copy of any omitted schedules will be furnished supplementally to the SEC upon request.

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

Item 16. Form 10-K Summary

None.

SIGNATURES

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

INVIVYD, INC.

Date: March 23, 2023

By: /s/ David Hering, M.B.A.
David Hering, M.B.A.
Chief Executive Officer and Director

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

Name	Title	Date
/s/ David Hering, M.B.A.	Chief Executive Officer and Director	March 23, 2023
David Hering, M.B.A.	*(Principal Executive Officer)*	
/s/ Frederick W. Driscoll	Interim Chief Financial Officer	March 23, 2023
Frederick W. Driscoll	*(Principal Financial Officer and Principal Accounting Officer)*	
/s/ Marc Elia	Chair of the Board of Directors	March 23, 2023
Marc Elia		
/s/ Tamsin Berry	Director	March 23, 2023
Tamsin Berry		
/s/ Tom Heyman	Director	March 23, 2023
Tom Heyman		
/s/ Christine Lindenboom	Director	March 23, 2023
Christine Lindenboom		
/s/ Terry McGuire	Director	March 23, 2023
Terry McGuire		
/s/ Clive A. Meanwell, M.D.	Director	March 23, 2023
Clive A. Meanwell, M.D.		
/s/ Michael S. Wyzga	Director	March 23, 2023
Michael S. Wyzga		

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Invivyd, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Invivyd, Inc. and its subsidiaries (the “Company”) as of December 31, 2022 and 2021, and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' equity (deficit) and of cash flows for the years then ended, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts

March 23, 2023

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

INVIVYD, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share amounts)

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	$ 92,076	$ 542,224
Marketable securities	279,915	49,194
Prepaid expenses and other current assets	4,926	25,293
Total current assets	376,917	616,711
Property and equipment, net	2,282	83
Operating lease right-of-use assets	3,777	—
Other non-current assets	191	3,297
Total assets	$ 383,167	$ 620,091
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 1,517	$ 5,783
Accrued expenses	21,911	56,277
Operating lease liabilities, current	1,559	—
Other current liabilities	44	—
Total current liabilities	25,031	62,060
Operating lease liabilities, non-current	2,165	—
Early-exercise liability	1	6
Other non-current liability	—	6
Total liabilities	27,197	62,072
Commitments and contingencies (Note 9)		
Stockholders' equity (deficit):		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at December 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 109,044,046 shares issued and outstanding at December 31, 2022; 1,000,000,000 shares authorized, 111,251,660 shares issued and 110,782,909 shares outstanding at December 31, 2021	11	11
Treasury stock, at cost; 0 shares and 468,751 shares at December 31, 2022 and December 31, 2021, respectively	—	—
Additional paid-in capital	889,657	850,125
Accumulated other comprehensive income (loss)	(272)	(8)
Accumulated deficit	(533,426)	(292,109)
Total stockholders' equity	355,970	558,019
Total liabilities, convertible preferred stock and stockholders' equity	$ 383,167	$ 620,091

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

INVIVYD, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share amounts)

	Year Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development[(1)]	$ 179,214	$ 182,891
Acquired in-process research and development[(2)]	4,400	7,500
Selling, general and administrative	47,044	36,517
Warrant expense[(3)]	17,373	—
Total operating expenses	248,031	226,908
Loss from operations	(248,031)	(226,908)
Other income (expense):		
Other income (expense), net	6,714	118
Total other income (expense), net	6,714	118
Net loss	(241,317)	(226,790)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities, net of tax	(264)	(8)
Comprehensive loss	$ (241,581)	$ (226,798)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.23)	$ (5.32)
Weighted-average common shares outstanding, basic and diluted	108,268,289	42,621,265

(1) Includes related-party amounts of $8,154 and $4,150 for the years ended December 31, 2022 and 2021, respectively (see Notes 7 and 8).
(2) Includes related-party amounts of $4,400 and $7,500 for the years ended December 31, 2022 and 2021, respectively (see Note 7).
(3) Includes related-party amounts of $17,373 and $0 for the years ended December 31, 2022 and 2021, respectively (see Note 8).

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

INVIVYD, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
Balances at December 31, 2021	—	—	110,782,909	11	468,751	—	850,125	(8)	(292,109)	558,019
Issuance of warrants for common stock	—	—	—	—	—	—	17,373	—	—	17,373
Exercise of stock options	—	—	298,353	—	—	—	241	—	—	241
Repurchase of unvested restricted common stock	—	—	(2,150,737)	—	2,150,737	—	—	—	—	—
Retirement of treasury stock	—	—	—	—	(2,619,488)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	21,648	—	—	21,648
Issuance of common stock under the employee stock purchase plan	—	—	113,521	—	—	—	269	—	—	269
Vesting of restricted common stock from early-exercised options	—	—	—	—	—	—	1	—	—	1
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	—	—	—	(264)	—	(264)
Net loss	—	—	—	—	—	—	—	—	(241,317)	(241,317)
Balances at December 31, 2022	—	$ —	109,044,046	$ 11	—	$ —	$ 889,657	$ (272)	$ (533,426)	$ 355,970

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

INVIVYD, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Treasury Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Equity (Deficit)
Balances at December 31, 2020	12,647,934	$ 169,548	5,593,240	$ 1	22,600,000	$ (85)	$ 154	$ —	$ (65,319)	$ (65,249)
Issuance of Series C convertible preferred stock, net of issuance costs of $337	4,296,550	335,163	—	—	—	—	—	—	—	—
Issuance of common stock	—	—	6,000	—	—	—	66	—	—	66
Issuance of common stock upon completion of initial public offering, net of commissions, underwriting discounts and offering costs	—	—	20,930,000	2	—	—	327,518	—	—	327,520
Conversion of convertible preferred stock to common stock	(16,944,484)	(504,711)	84,722,420	8	—	—	504,703	—	—	504,711
Retirement of treasury stock	—	—	—	—	(22,600,000)	$ 85	(85)	—	—	—
Vesting of restricted common stock from early-exercised options	—	—	—	—	—	—	5	—	—	5
Repurchase of unvested restricted common stock	—	—	(468,751)	—	468,751	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	17,764	—	—	17,764
Unrealized loss on available-for-sale securities, net of tax	—	—	—	—	—	—	—	(8)	—	(8)
Net loss	—	—	—	—	—	—	—	—	(226,790)	(226,790)
Balances at December 31, 2021	—	$ —	110,782,909	$ 11	468,751	$ —	$ 850,125	$ (8)	$ (292,109)	$ 558,019

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

INVIVYD, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (241,317)	$ (226,790)
Adjustments to reconcile net loss to net cash used in operating activities:		—
Stock-based compensation expense	21,648	17,764
Warrant expense	17,373	—
Net amortization of premiums and accretion of discounts on marketable securities	(2,023)	1,430
Amortization of operating lease right-of-use assets	421	—
Non-cash payments	—	66
Depreciation expense	41	1
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	20,367	(22,899)
Other non-current assets	3,106	(3,297)
Accounts payable	(4,300)	(2,370)
Accrued expenses	(34,867)	51,358
Operating lease liabilities	(475)	—
Other current liabilities	44	—
Other non-current liabilities	(5)	1
Net cash used in operating activities	(219,987)	(184,736)
Cash flows from investing activities:		
Purchases of marketable securities	(297,962)	(188,627)
Maturities of marketable securities	69,000	138,000
Purchases of property and equipment	(1,705)	(84)
Net cash used in investing activities	(230,667)	(50,711)
Cash flows from financing activities:		
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	335,163
Proceeds from issuance of common stock, net of commissions and underwriting discounts	—	330,905
Payments of initial public offering costs	—	(3,385)
Proceeds from exercises of stock options	241	—
Proceeds from issuance of common stock under the employee stock purchase plan	269	—
Payments for repurchases of unvested restricted common stock	(4)	—
Net cash provided by financing activities	506	662,683
Net (decrease) increase in cash and cash equivalents	(450,148)	427,236
Cash and cash equivalents at beginning of period	542,224	114,988
Cash and cash equivalents at end of period	$ 92,076	$ 542,224
Supplemental disclosure of cash flow information:		
Operating lease right-of-use asset recognized upon adoption of ASC 842	$ 1,728	$ —
Operating lease right-of-use asset recognized under ASC 842	$ 2,470	$ —
Supplemental disclosure of non-cash investing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 535	$ —

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

1. Nature of the Business and Basis of Presentation

Invivyd, Inc., (formerly Adagio Therapeutics, Inc.) together with its consolidated subsidiaries (the "Company"), is a biopharmaceutical company on a mission to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats, beginning with SARS-CoV-2 ("COVID-19"). The Company's technology works at the intersection of evolutionary virology, predictive modeling, and antibody engineering, and is designed to identify high-quality, long-lasting antibodies with a high barrier to viral escape. The Company is generating a robust pipeline of product candidates which could be used in prevention or treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications.

In March 2023, the Company announced the election of VYD222 to advance into the clinic as a monoclonal antibody ("mAb") therapeutic option for COVID-19 with a focus on serving vulnerable populations. The Company aims to leverage evolving COVID-19 regulatory paradigms and maximize efficiency to deliver this much-needed product for immunocompromised individuals and other vulnerable populations.

VYD222 is one of two mAb components of NVD200, a combination mAb product candidate that the Company previously selected for clinical advancement prior to evolution in the current global COVID-19 regulatory paradigm. The Company is prioritizing the clinical development of VYD222 instead of NVD200 with the aim of providing patients with a therapeutic option for COVID-19 as quickly and efficiently as possible. VYD222 was engineered from adintrevimab, the Company's investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 3 clinical trials for both the prevention and treatment of COVID-19.

Beyond VYD222, the Company continues to leverage its expanded lab capabilities and integrated discovery platform to produce additional candidates that will be optimized to stay ahead of the evolving SARS-CoV-2 virus. In addition, the Company continues to work with regulatory agencies to streamline the development and commercialization plans for novel antibodies to protect immunocompromised and other high-risk populations against the evolving SARS-CoV-2 virus.

The Company was incorporated in the State of Delaware in June 2020. The Company operates as a virtual company and maintains a corporate headquarters for general and administrative purposes only. In June 2022, and subsequently amended in September 2022, the Company entered into a lease for dedicated laboratory and office space in Newton, MA for research and development purposes. The Company performs research and development activities internally and engages third parties, including Adimab, LLC ("Adimab"), to perform ongoing research and development and other services on its behalf.

The Company is subject to a number of risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including, but not limited to, completing clinical trials, the ability to raise additional capital to fund operations, obtaining regulatory approval for product candidates, market acceptance of products, competition from substitute products, protection of proprietary intellectual property, compliance with government regulations, the impact of COVID-19, dependence on key personnel, the ability to attract and retain qualified employees, and reliance on third-party organizations for the discovery, manufacturing, clinical and commercial success of its product candidates.

In July 2021, the Company effected a five-for-one stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 10). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the preferred stock conversion ratios.

In August 2021, the Company completed its initial public offering ("IPO") pursuant to which it issued and sold 20,930,000 shares of its common stock, including 2,730,000 shares pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were approximately $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all shares of the Company's convertible preferred stock then outstanding converted into 84,722,420 shares of common stock (see Note 11).

The Company has not generated any revenue since inception. The Company's product candidates require significant additional research and development efforts, including extensive clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and compliance-reporting capabilities. Even if the Company's development efforts are successful, it is uncertain when, if ever, the Company will generate revenue from product sales, including government supply contracts.

The accompanying consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. The Company has primarily funded its operations with proceeds from sales of convertible preferred stock and proceeds from the Company's initial public offering of common stock. The Company has incurred losses and negative cash flows from operations since its inception, including a net loss of $241.3 million for the year ended December 31, 2022. As of December 31, 2022, the Company had an accumulated deficit of $533.4 million. The Company expects to continue to generate operating losses for the foreseeable future. As of March 23, 2023, the issuance date of the consolidated financial statements for the year ended December 31, 2022, the Company expects that its cash, cash equivalents and marketable securities, would be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of the annual consolidated financial statements.

The Company expects to seek additional funding through a combination of equity offerings, government or private-party grants, debt financings or other capital sources, including collaborations with other companies, strategic alliances and licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any financing may adversely affect the holdings or rights of the Company's stockholders.

If the Company is unable to obtain sufficient capital, the Company will be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

Impact of COVID-19 on Our Operations

The full impact of the COVID-19 pandemic and the disease continues to evolve and change as of the date of this Annual Report on Form 10-K, and such impact will directly affect the potential commercial prospects of VYD222 and other product candidates for the prevention and treatment of COVID-19. The severity of the COVID-19 pandemic, the evolution of the disease and the continued emergence of variants of concern ("VoCs"), the availability, administration and acceptance of vaccines, monoclonal antibodies, antiviral agents and other therapeutic modalities, vaccine mandates by employers and/or local or national governments, 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.

Similarly, it is not possible to determine the scale and rate of economic recovery from the pandemic, supply chain disruptions, and labor availability and costs, or the impact of other indirect factors that may be attributable to the pandemic. 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 uncertain and will depend on future developments, including the duration and spread of outbreaks and the continued emergence of variants, its impact on the Company's clinical trial design and enrollment, trial sites, contract research organizations ("CROs"), contract development and manufacturing organizations ("CDMOs"), and other third parties with which the Company does business, as well as its impact on regulatory authorities and the Company's key scientific and management personnel. To date, the Company has experienced some delays and disruptions in its development activities as a result of the COVID-19 pandemic. Some of the Company's CROs, CDMOs and other service providers also continue to be impacted. The Company will continue to monitor developments as it addresses the disruptions, delays and uncertainties relating to the COVID-19 pandemic. If the financial markets and/or the overall economy are impacted for an extended period, the Company's results and operations may be materially adversely affected and may affect the Company's ability to raise capital.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements include the accounts of Invivyd, Inc. and its wholly owned subsidiaries, Invivyd Security Corporation, Invivyd Switzerland GmbH, and Invivyd Netherlands B.V. All intercompany accounts and transactions have been eliminated in consolidation. The Company views its operations and manages its business in one operating segment, which is the business of discovering, developing and commercializing differentiated products for the prevention and treatment of infectious diseases.

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, stock-based compensation expense and warrant expense. The Company bases its estimates on historical experience, known trends and other market-specific or relevant factors it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ materially from those estimates or assumptions.

The Company is monitoring the potential impact of the COVID-19 pandemic on its business and consolidated financial statements. The Company is not aware of any specific event or circumstance that would require any update to its estimates or judgments reflected in these consolidated financial statements or a revision of the carrying value of its assets or liabilities as of the issuance date of these consolidated financial statements. These estimates may change as new events occur and additional information is obtained.

Concentrations of Credit Risk, Significant Suppliers and License Rights

Financial instruments that potentially expose the Company to concentrations of credit risk consist of cash, cash equivalents and marketable securities. The Company invests its excess cash in money market funds and marketable securities that are subject to minimal credit and market risks. The Company maintains its cash, cash equivalents and marketable securities at two accredited financial institutions that it believes are creditworthy. From time to time, these deposits may exceed federally insured limits. The Company has not experienced any losses historically in these accounts. Accordingly, the Company does not believe it is exposed to unusual credit risk related to its cash, cash equivalents and marketable securities beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party organizations to manufacture and process its product candidates for its development programs. In particular, the Company relies on a single third-party contract manufacturer to produce and process its product candidates and to manufacture supply of its product candidates for preclinical and clinical activities (see Note 9). The Company also currently relies on this same third-party contract manufacturer for any anticipated requirements of commercial supply, including both drug substance and drug product. The Company expects to continue to be dependent on a small number of manufacturers to supply it with its requirements for all products. The Company's research and development programs, including any associated potential commercialization efforts, could be adversely affected by a significant interruption in the supply of the necessary materials.

The Company is dependent on a limited number of third parties that provide license rights used by the Company in the development and potential commercialization of its product candidates and programs. Through December 31, 2022, the Company's research and development programs primarily relate to rights conveyed by Adimab (see Note 7). The Company could experience delays in the development and potential commercialization of its product candidates and programs if the Adimab agreements or any other license agreement utilized in the Company's research and development activities is terminated, if the Company fails to meet the obligations required under its arrangements, or if the Company is unable to successfully secure new strategic alliances or licensing agreements.

Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less at the acquisition date to be cash equivalents.

Marketable Securities

Marketable securities represent holdings of available-for-sale marketable debt securities in accordance with the Company's investment policy. The Company determines the appropriate classification of marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. The Company classified all of its marketable securities at December 31, 2022 as "available-for-sale" pursuant to ASC320, Investments – Debt and Equity Securities. Investments not classified as cash equivalents are presented as either short-term or long-term investments based on both their maturities as well as the time period the Company intends to hold such securities. Available-for-sale securities are maintained by an investment manager and consist of U.S. Treasury securities and federal agency securities. Available-for-sale securities are carried at fair value with the unrealized gains and losses included in other comprehensive income (loss) as a component of stockholders' equity (deficit) until realized. Any premium or discount arising at purchase is amortized or accreted to interest expense or income over the life of the instrument. Realized gains and losses are determined using the specific identification method and are included in other income (expense). There were no material realized gains or losses on marketable securities recognized for the year ended December 31, 2022.

The Company reviews marketable securities for other-than-temporary impairment whenever the fair value of a marketable security is less than the amortized cost and evidence indicates that a marketable security's carrying amount is not recoverable within a reasonable period of time. Other-than-temporary impairments of investments are recognized in the consolidated statements of operations and comprehensive loss if the Company has experienced a credit loss, has the intent to sell the marketable security, or if it is more likely than not that the Company will be required to sell the marketable security before recovery of the amortized cost basis. Evidence considered in this assessment includes reasons for the impairment, compliance with the Company's investment policy, the severity and duration of the impairment and changes in value subsequent to the end of the period. There were no other-than-temporary impairments of investments recognized for the years ended December 31, 2022 or 2021.

Fair Value Measurements

Certain assets of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and marketable securities are carried at fair value, determined according to the fair value hierarchy described above (see Note 4). The carrying values of the Company's accounts payable and accrued expenses approximate their fair values due to the short-term nature of these liabilities.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation and amortization expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Machinery and equipment	3 to 5 years
Furniture and fixtures	3 to 5 years
Leasehold improvements	Shorter of lease term of useful life

Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated in accordance with the above guidelines once placed into service. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation and amortization are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance that do not improve or extend the life of the respective assets are charged to expense as incurred.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. The Company continually evaluates long-lived assets for potential impairment whenever events or changes in circumstances indicate that the carrying value of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset group for recoverability, the Company compares the carrying values of the asset group to the expected future undiscounted cash flows that the asset group is expected to generate from the use and eventual disposition of the long-lived asset group. An impairment loss would be recognized in loss from operations when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. If such asset group is considered to be impaired, the impairment loss to be recognized would be based on the excess of the carrying value of the impaired asset group over its fair value. The Company did not recognize any impairment losses on long-lived assets during the years ended December 31, 2022 and 2021.

Leases

Effective January 1, 2022, the Company adopted ASU No. 2016-02, Leases (Topic 842) (“ASC 842”) using the required modified retrospective approach and utilizing the effective date as its date of initial application. As a result, prior periods are presented in accordance with the previous guidance in ASC 840, Leases (“ASC 840”).

The Company evaluates whether an arrangement is or contains a lease at the inception date. If determined to be or contain a lease, the Company determines the classification of the lease at the commencement date, which represents the date at which the lessor makes the underlying asset available for use by the Company. When determining the expected accounting lease term, the Company includes the noncancellable lease term, together with periods covered by (i) an option to extend the lease if the Company is reasonably certain to exercise such option, (ii) an option to terminate the lease if the Company is reasonably certain not to exercise such option and (iii) an option to extend or not terminate the lease where the exercise of such option is controlled by the lessor. The Company has elected the short-term lease exemption, which allows the Company to not recognize lease liabilities and right-of-use assets arising from lease arrangements with original lease terms of twelve months or less. The Company elected the practical expedient to not separate lease and non-lease components for its leases.

Right-of-use assets represent the Company’s right to use an underlying asset over the lease term and lease liabilities represent the Company’s obligation to make lease payments under the arrangement. The Company measures its lease liabilities as the present value of the lease payments, discounted using an incremental borrowing rate, as interest rates implicit in lease arrangements are generally not readily determinable. The Company measures its right-of-use assets as the present value of its lease payments at the commencement date. The incremental borrowing rate represents the interest rate at which the Company could borrow an amount equal to the lease payments on a fully collateralized basis, over a similar term, in a similar economic environment. The Company recognizes rent expense for operating leases on a straight-line basis. The Company recognizes variable lease expenses as incurred.

The Company remeasures right-of-use assets and lease liabilities when a lease is modified, and the modification is not accounted for as a separate contract. A modification is accounted for as a separate contract if the modification grants the Company an additional right of use not included in the original lease arrangement and the increase in lease payments is commensurate with the additional right of use. The Company assesses its right-of-use assets for impairment in a manner consistent with its assessment for long-lived assets held and used in operations.

Patent Costs

Costs to secure, defend and maintain patents, including those incurred in connection with filing and prosecuting patent applications, are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred for patent-related expenditures are classified as general and administrative expenses.

Segment Information

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company is focused on the discovery, development and commercialization of antibody-based solutions for infectious diseases with pandemic potential. The Company's chief operating decision maker reviews the Company's financial information on an aggregated basis for purposes of assessing performance and allocating resources.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses consist of costs incurred in performing research and development activities, including expenses incurred under agreements with external vendors and consultants engaged to perform non-clinical studies, preclinical studies and clinical trials as well as to manufacture research and development materials for use in such studies and trials; salaries and related personnel costs; stock-based compensation; consultant fees; and third-party license fees.

Nonrefundable advance payments for goods and services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Accrued Research and Development Costs

The Company has entered into various research, development and manufacturing contracts with third-party service providers, including contract research organizations and contract manufacturing organizations. With the exception of the Company's manufacturing arrangement with WuXi Biologics (Hong Kong) Limited (see Note 9), 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.

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, 2022.

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.

Warrant Expense

The Company recognizes stock-based compensation for warrants granted to non-employee service providers based upon the awards' estimated grant date fair value. The warrants vest subject to the satisfaction of service-based conditions. Warrant expense is measured based on the fair value of the award on the date of grant and expense is recognized on a straight-line basis over the requisite service period, which varies for each non-employee service provider on a grant-by-grant basis.

The Company accounts for forfeitures as they occur. The Company classifies stock-based compensation for non-employee service providers as warrant expense in its statements of operations and comprehensive loss.

The Company estimates the fair value of warrants using the Geometric Brownian Motion model. The assumptions used in estimating the fair value of these awards, such as expected term, expected dividend yield, volatility, and risk-free interest rate represent management's best estimates and involve inherent uncertainties and the application of management's judgment. If actual results are not consistent with the Company's assumptions and judgments used in making these estimates, the Company may be required to increase or decrease warrant expense, which could be material to the Company's consolidated results of operations.

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, 2022 and 2021.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity (deficit) that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2022 and 2021, the Company's only element of other comprehensive loss was unrealized losses on marketable securities.

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 convertible preferred stock, outstanding stock options, unvested restricted common stock and outstanding warrants 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 Issued and Adopted Accounting Pronouncements

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (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 its initial public offering. However, if certain events occur prior to the end of such five-year period, including if it becomes a "large accelerated filer," its annual gross revenues exceeds $1.235 billion or it issues more than $1.0 billion of non-convertible debt in the previous three-year period, it will cease to be an emerging growth company prior to the end of such five-year period. For so long as the Company remains an emerging growth company, it is permitted and intends to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. For example, 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.

In February 2016, the FASB issued 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 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. A lessee is also required to record (i) a right-of-use asset and a lease liability on its balance sheets for all leases with a term of greater than 12 months regardless of their classification and (ii) lease expense on its statement of operations for operating leases and amortization and interest expense on its statement of operations for financing leases. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases under ASC 840. The Company adopted the new standard and used the modified retrospective approach with January 1, 2022 as the initial date of application. The Company elected the available package of practical expedients which allowed the Company to not reassess previous accounting conclusions around whether arrangements are or contain leases, the classification of leases, and the treatment of initial direct costs. As a result of the adoption of ASC 842, the Company recorded (i) an operating lease liability, current of $0.3 million, (ii) an operating lease liability, non-current of $1.4 million and (iii) an operating lease right-of-use asset of $1.7 million, net of the unamortized balance of deferred rent liability as of the transition date. There was no impact from the adoption of ASC 842 to the Company's results of operations and cash flows from operations. A summary of the impact of the adoption is as follows (in thousands):

	December 31, 2021	Impact of Adoption	January 1, 2022
Operating lease right-of-use asset	$ —	$ 1,728	$ 1,728
Operating lease liability, current	—	308	308
Other non-current liability	6	(6)	—
Operating lease liability, non-current	—	1,426	1,426

3. Marketable Securities

Marketable securities held by the Company are classified as available-for-sale debt securities pursuant to ASC 320, Investments – Debt and Equity Securities, and carried at fair value in the accompanying consolidated balance sheets on a settlement date basis.

The following tables summarize the gross unrealized gains and losses of the Company's marketable securities as of December 31, 2022 and 2021 (in thousands):

December 31, 2022	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury securities	$ 107,973	$ 13	$ (115)	$ 107,871
Federal agency securities	172,214	39	(209)	172,044
Total financial assets	$ 280,187	$ 52	$ (324)	$ 279,915

December 31, 2021	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
U.S. Treasury securities	$ 49,202	$ —	$ (8)	$ 49,194

No available-for-sale marketable securities held as of December 31, 2022 or 2021 had remaining maturities greater than twelve months.

4. Fair Value Measurements

The following tables present the Company's fair value hierarchy for its assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at December 31, 2022:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 91,050	$ —	$ —	$ 91,050
Marketable securities:				
U.S. Treasury securities	$ 107,871	—	—	$ 107,871
Federal agency securities	—	172,044	—	$ 172,044
	$ 198,921	$ 172,044	$ —	$ 370,965

	Fair Value Measurements at December 31, 2021:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 541,220	$ —	$ —	$ 541,220
Marketable securities:				
U.S. Treasury securities	49,194	—	—	49,194
	$ 590,414	$ —	$ —	$ 590,414

As of December 31, 2022 and 2021, the money market funds and U.S. Treasury securities were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy.

As of December 31, 2022, the Company's marketable securities also consisted of federal agency securities, which were valued based on Level 2 inputs. In determining the fair value of its federal agency securities, the Company relied on quoted prices for similar securities in active markets or other inputs that are observable or can be corroborated by observable market data. Since Federal agency securities typically do not trade as U.S. government agency securities and no exchange exists to price such investments, they are recognized as Level 2 assets.

There were no changes to the valuation methods during the years ended December 31, 2022 or 2021.

The Company evaluates transfers between levels at the end of each reporting period. There were no transfers into or out of Level 1, Level 2 or Level 3 fair value measurements during the years ended December 31, 2022 or 2021.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	December 31,	
	2022	2021
Prepaid external research, development and manufacturing costs	$ 843	$ 20,582
Prepaid insurance	2,392	3,190
Prepaid compensation and other	1,314	1,292
Interest receivable	377	229
	$ 4,926	$ 25,293

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2022	2021
Accrued external research, development and manufacturing costs	$ 13,955	$ 48,590
Accrued professional and consultant fees	1,153	2,155
Accrued employee compensation	5,985	4,945
Other	818	587
	$ 21,911	$ 56,277

7. License and Collaboration Agreements

Adimab Assignment Agreement

In July 2020, the Company entered into an Assignment and License Agreement with Adimab (the "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 (each, a "CoV Antibody" and together, the "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.

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 years ended December 31, 2022 and 2021, the Company recognized $0.6 million and $1.3 million, respectively, of research and development expense in connection with services performed by Adimab on the Company's behalf. Please refer to Note 16 for additional information.

In July 2020, in consideration for the rights assigned and license conveyed under the Adimab Assignment Agreement, the Company issued 5,000,000 shares of its Series A convertible preferred stock (the "Series A Preferred Stock"), then having

a fair value of $40.0 million, to Adimab. Concurrently, Adimab relinquished 21,250,000 shares of the Company's common stock to the Company, then having a fair value of $85,000. Additionally, the Company is obligated to pay Adimab up to $16.5 million upon the achievement of specified development and regulatory milestones for the first Product under the agreement that achieves such specified milestones and up to $8.1 million upon the achievement of specified development and regulatory milestones for the second Product under the agreement that achieves such specified milestones. The maximum aggregate amount of milestone payments payable under the agreement for any and all Products is $24.6 million; however, milestone payments do not accrue for certain *in vitro* diagnostic devices consisting of or containing CoV Antibodies.

In February 2021, the Company achieved the first specified milestone under the agreement upon dosing of the first patient in a Phase 1 global clinical trial evaluating adintrevimab, which obligated the Company to make a $1.0 million milestone payment to Adimab. In April 2021, the Company achieved the second specified milestone under the agreement upon dosing of the first patient in a Phase 2 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated the Company to make a $2.5 million milestone payment to Adimab. In August 2021, the Company achieved the third specified milestone under the agreement upon dosing of the first patient in a Phase 3 global clinical trial evaluating adintrevimab for the prevention of COVID-19, which obligated the Company to make a $4.0 million milestone payment to Adimab. The Company recognized each expense when achievement of each of the first, second and third milestones became probable of achievement in February, April and August 2021, respectively. The next potential milestone under the Adimab Assignment Agreement is a low six-digit dollar milestone related to dosing of the first subject in a Phase 1 trial, which was not considered probable as of December 31, 2022.

For the year ended December 31, 2022, the Company did not recognize any IPR&D expense in connection with contingent consideration payable under the Adimab Assignment Agreement. For the year ended December 31, 2021, the Company recognized $7.5 million as IPR&D expense in connection with contingent consideration payable under the Adimab Assignment Agreement.

The Company is obligated to pay Adimab royalties of a mid-single-digit percentage based on net sales of any Products, once commercialized. The royalty rate is subject to reductions specified under the agreement. Royalties are due on a Product-by-Product and country-by-country basis beginning upon the first commercial sale of each Product and ending on the later of (i) 12 years after the first commercial sale of such Product in such country and (ii) the expiration of the last valid claim of a patent covering such Product in such country ("Royalty Term"). In addition, the Company is obligated to pay Adimab royalties of a specified percentage in the range of 45% to 55% of any compulsory sublicense consideration received by the Company in lieu of certain royalty payments. Except for the first milestone payment of $1.0 million, the second milestone payment of $2.5 million and the third milestone payment of $4.0 million, which were paid by the Company to Adimab in March, May and September 2021, respectively, no other milestone, royalty or other contingent payments had become due to Adimab through December 31, 2022.

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, or in the event of a material breach by Adimab that is not cured with specific periods. 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.

Adimab Collaboration Agreement

In May 2021, the Company entered into a Collaboration Agreement with Adimab, as amended in November 2022 (the "Adimab Collaboration Agreement") for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Collaboration Agreement, the Company and Adimab will collaborate on research programs for a specified number of targets selected by the Company within a specified time period. Under the Adimab Collaboration Agreement, Adimab granted the Company a worldwide, non-exclusive license to certain of its platform patents and technology and antibody patents to perform the Company's responsibilities during the ongoing research period and for a specified evaluation period thereafter (the "Evaluation Term"). In addition, the Company granted Adimab a license to certain of the Company's patents and intellectual property solely to perform Adimab's responsibilities under the research plans. Under the Adimab Collaboration 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 optioned research program.

The Company is obligated to pay Adimab a quarterly fee of $1.3 million, which may be cancelled at the Company's option at any time. For so long as the Company is paying such quarterly fee (or earlier if (i) the Company experiences a change of control after the third anniversary of the Adimab Collaboration Agreement or (ii) Adimab owns less than a specified percentage of the Company's equity), Adimab and its affiliates will not assist or direct certain third parties to discover or optimize antibodies that are intended to bind to coronaviruses or influenza viruses. The Company may also elect to decrease the scope of Adimab's exclusivity obligations and obtain a corresponding decrease in the quarterly fee. For the years ended December 31, 2022 and 2021, the Company recognized $5.2 million and $2.6 million, respectively, of research and development expense related to the quarterly fee.

For each agreed upon research program that is commenced, the Company is obligated to pay Adimab quarterly for its services performed during a given research program at a specified full-time equivalent rate; a discovery delivery fee of $0.2 million; and an optimization completion fee of $0.2 million. For each option exercised by the Company to commercialize a specific research program, the Company is obligated to pay Adimab an exercise fee of $1.0 million. Amounts paid with respect to services performed by Adimab on the Company's behalf in each of the research programs under the Adimab Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. For the years ended December 31, 2022 and 2021, the Company recognized $1.7 million and $0.3 million, respectively, of research and development expense in connection with services performed by Adimab on the Company's behalf. Through December 31, 2022, the Company recognized $0.4 million and $1.0 million of IPR&D expense related to drug delivery fees and an option exercise, respectively. Additionally, through December 31, 2022, the Company has not paid an optimization completion fee to Adimab. Please refer to Note 16 for additional information.

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 Adimab Collaboration Agreement that achieves such milestones. The next potential milestone under the Adimab Collaboration Agreement is a low single-digit million dollar milestone related to dosing of the first subject in a Phase 1 trial, which was not considered probable as of December 31, 2022. The Company is also obligated to pay Adimab royalties of a mid-single-digit percentage based on net sales of any product under the Adimab Collaboration Agreement, subject to reductions for third-party licenses. The royalty term will expire for each product on a country-by-country basis upon the later of (i) 12 years after the first commercial sale of such product in such country and (ii) the expiration of the last valid claim of any patent claiming composition of matter or method of making or using any antibody identified or optimized under the Adimab Collaboration Agreement in such country.

In addition, the Company is obligated to pay Adimab for Adimab's performance of certain validation work with respect to certain antigens acquired from a third party. In consideration for this work, the Company is obligated to pay Adimab royalties of a low single-digit percentage based on net sales of products that contain such antigens for the same royalty term as antibody-based products, but the Company is not obligated to make any milestone payments for such antigen products. Through December 31, 2022, the Company had not paid any royalties to Adimab under the Adimab Collaboration Agreement.

The Adimab Collaboration Agreement will expire (i) if the Company does not exercise any option, upon the conclusion of the last Evaluation Term for the research programs, or (ii) if the Company exercises an option, on the expiration of the last royalty term for a product in a particular country, unless the agreement is earlier terminated. The Company may terminate the Adimab Collaboration Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either party may terminate the Adimab Collaboration Agreement in the event of a material breach by the other party that is not cured within specified periods.

The Company concluded that the Adimab Collaboration Agreement represented an asset acquisition of IPR&D with no alternative future use. Therefore, payments made by the Company to Adimab for milestones achieved will be recognized as acquired IPR&D expense in the related period in which the services are performed or the related milestone is considered probable of achievement. Amounts paid with respect to services performed by Adimab on the Company's behalf under the

Adimab Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. Please refer to Note 16 for additional information.

Adimab Platform Transfer Agreement

In September 2022 ("Effective Date"), the Company entered into a Platform Transfer Agreement with Adimab (the "Adimab Platform Transfer Agreement") under which the Company was granted the right under certain intellectual property of Adimab to practice certain elements of Adimab's platform technology, including B-cell cloning using Adimab's proprietary yeast cell lines and other antibody optimization libraries, trade secrets, protocols and software of Adimab, to discover, engineer and optimize antibodies. The Company does not have access to Adimab's proprietary discovery libraries. The Company was also granted the right under certain intellectual property of Adimab to research, develop, make, sell and exploit such antibodies and products containing such antibodies. The Adimab platform will be transferred to the Company in accordance with the terms of the Adimab Platform Transfer Agreement. In September 2022, the Company recognized $3.0 million as IPR&D expense in connection with the upfront consideration payable for the rights assigned pursuant to the Adimab Platform Transfer Agreement.

The Company is obligated to pay Adimab an annual fee of single digit millions on each of the first four anniversaries of the Effective Date, which will allow the Company to receive material improvements to the platform technology, including materially improved antibody optimization libraries, updates that provide new functionality to the platform, and software upgrades, from Adimab through June 2027. The first annual fee will become due in September 2023. Beginning in July 2027 and ending in June 2042, unless terminated earlier, the Company has the option to receive additional material improvements to the platform technology from Adimab, subject to a commercially reasonable fee to be negotiated by the parties.

The Company is obligated to pay Adimab up to $9.5 million upon the achievement of specified development and regulatory milestones for each product under the Adimab Platform Transfer Agreement that achieves such milestones. The next potential milestone under the Adimab Platform Transfer Agreement is a mid-six-digit dollar milestone related to the start of IND-enabling toxicology studies, which was not considered probable as of December 31, 2022.

In addition, the Company is obligated to pay Adimab royalties of a low single-digit percentage based on net sales of products containing an antibody discovered, engineered or optimized using Adimab's platform technology, once commercialized. The royalty rate is subject to reductions specified under the Adimab Platform Transfer Agreement. Royalties are due on a product-by-product and country-by-country basis. 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 a program antibody patent for covering the program antibody contained in such product in such country. Through December 31, 2022, the Company had not paid any royalties to Adimab under the Adimab Platform Transfer Agreement.

The Company may terminate the Adimab Platform Transfer Agreement at any time upon advance written notice to Adimab. In addition, subject to certain conditions, either party may terminate the Adimab Platform Transfer Agreement in the event of a material breach by the other party that is not cured within specified periods or in connection with the other party's insolvency.

The Company concluded that the Adimab Platform Transfer Agreement represented an asset acquisition of IPR&D with no alternative future use. Therefore, payments made by the Company to Adimab for milestones achieved will be recognized as acquired IPR&D expense in the related period in which the services are performed or the related milestone is considered probable of achievement. Amounts paid with respect to the annual material improvement fees are recognized as research and development expense as such amounts are incurred. Please refer to Note 16 for additional information.

WuXi Biologics Cell Line License Agreement

In December 2020, as amended in February 2023, the Company entered into a Cell Line License Agreement with WuXi Biologics (Hong Kong) Limited ("WuXi Biologics") (the "Cell Line License Agreement"), under which WuXi Biologics 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 Biologics 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 Biologics (each of such transformed or transfected cell lines, a "Licensed Cell Line").

The Company paid an upfront fee of $0.2 million to WuXi Biologics upon completion of cell bank generation for the first Licensed Cell Line created under the Cell Line License Agreement. The Company is also obligated to pay royalties in the range of less than 1.0% to WuXi Biologics 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 Biologics to manufacture all of its commercial supplies for

Licensed Products, no royalties would be owed by the Company to WuXi Biologics 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 in the low eight-figures to WuXi Biologics. 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 continuing for so long as the Company commercializes Licensed Products or, if earlier, until the Company exercises its option to buy out the royalty obligations. Through December 31, 2022, no royalties had become due to WuXi Biologics.

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 Biologics. WuXi Biologics may terminate the Cell Line License Agreement in the event the Company fails to make a payment when due under the Cell Line License Agreement 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 Biologics 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 Cell Line License Agreement, 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 Cell Line License Agreement did not qualify as a business combination because substantially all of the fair value of the assets acquired was concentrated in a single asset. Therefore, the aggregate acquisition cost of $0.2 million, consisting solely of the upfront fee, was recognized as acquired IPR&D expense for the period from June 3, 2020 (inception) to December 31, 2020.

Research Collaboration and License Agreement with The Scripps Research Institute

In August 2021, the Company entered into a Research Collaboration and License Agreement (the “Research Agreement”) with The Scripps Research Institute (“TSRI”). Under the terms of the Research Agreement, TSRI performed research activities to identify vaccine candidates for the prevention, diagnosis or treatment of influenza or beta coronaviruses. In August 2021, the Company paid TSRI $1.5 million in funding, which was credited against research funding payable by the Company under the Research Agreement.

In April 2022, the Company provided written notice to TSRI to terminate the Research Agreement. Following early termination in the second quarter of 2022, all licenses were terminated and reverted to TSRI.

Amounts incurred for services performed by TSRI under the Research Agreement were expensed to research and development expense as the services were rendered. During the years ended December 31, 2022 and December 31, 2021, the Company recognized $1.7 million and $2.3 million, respectively, of research and development expense associated with services performed under the Research Agreement.

8. Population Health Partners, L.P

In November 2022 (the “PHP Effective Date”), the Company entered into a Master Services Agreement with Population Health Partners, L.P. (“PHP”), pursuant to which PHP agreed to provide services and create deliverables for the Company as agreed between the Company and PHP and set forth in one or more work orders under such agreement (the “PHP MSA”). The term of the PHP MSA commenced on the PHP Effective Date and will continue for a period of one year, unless terminated earlier in accordance with its terms. On the PHP Effective Date, the Company and PHP entered into the first work order under the PHP MSA (the “PHP Work Order”), pursuant to which PHP agreed to advise and counsel the Company regarding clinical development and regulatory matters with respect to the Company’s product candidates. The PHP Work Order is effective for six months from the Effective Date and may be extended by written agreement of the Company and PHP. The PHP MSA contains customary confidentiality provisions and representations and warranties of the parties, as well as mutual non-solicitation of certain employees during the term of the PHP MSA and for a period of one year thereafter.

As compensation for the services and deliverables under the PHP Work Order, the Company shall pay PHP a cash fee of $0.5 million per month during the term of the PHP Work Order for an aggregate fee of $3.0 million (the “Aggregate Fee”). In the event that (i) the Company terminates the PHP Work Order for any reason other than material breach by PHP or (ii) PHP terminates the PHP Work Order due to material breach by the Company, in each case, pursuant to the terms of the PHP MSA, the Company would be required to pay PHP the balance of the Aggregate Fee as of the date the PHP Work Order is terminated. The cash fee is subject to change if the parties extend the term of the PHP Work Order in accordance with the terms thereof.

For the year ended December 31, 2022, the Company recognized $0.8 million of research and development expense related to the cash compensation paid to PHP.

In addition to the cash compensation, on the PHP Effective Date, the Company issued a warrant to purchase shares of the Company's common stock to PHP (the "PHP Warrant"). The exercise price of the PHP Warrant is $3.48 per share of Common Stock, which is equal to the Nasdaq Official Closing Price of a share of Common Stock on the trading day immediately prior to the PHP Effective Date. The PHP Warrant is exercisable for up to an aggregate of 6,824,712 shares of Common Stock, and vests in three separate tranches as follows:

- 3,591,954 shares of the Company's common stock underlying the PHP Warrant vests if the Company's Market Capitalization (as defined below) equals or exceeds $758,517,511 by November 15, 2028;
- 1,795,977 shares of the Company's common stock underlying the PHP Warrant vests if the Company's Market Capitalization equals or exceeds $1,137,776,266 by November 15, 2029; and
- 1,436,781 shares of the Company's common stock underlying the PHP Warrant vests if the Company's Market Capitalization equals or exceeds $1,517,035,022 by November 15, 2030.

For purposes of the PHP Warrant, the term "Market Capitalization" means, with respect to a particular trading day, the total value of the outstanding shares of Common Stock on such date, calculated by multiplying the Company's volume weighted average price for the ten (10) trading days immediately preceding such date by the Company's total number of outstanding shares of Common Stock as reflected in (i) the Company's most recent periodic or annual report filed with the U.S. Securities and Exchange Commission ("SEC") (e.g., Annual Report on Form 10-K or Quarterly Report on Form 10-Q), as the case may be, (ii) a more recent public announcement by the Company or (iii) a more recent written notice by the Company or the Company's transfer agent setting forth the number of shares of the Company's common stock outstanding.

The PHP Warrant is exercisable for ten years from the PHP Effective Date with respect to the vested portion(s) of the PHP Warrant. The PHP Warrant may be exercised by cash exercise or, at the election of PHP, by means of "cashless exercise" pursuant to a formula set forth in the PHP Warrant. The Company has also granted PHP certain "piggyback" registration rights requiring the Company to register any shares of the Company's common stock underlying the Warrant for resale with the SEC, subject to the Company's existing obligations under that certain Second Amended and Restated Investors' Rights Agreement, dated April 16, 2021, by and among the Company and the investors party thereto.

Upon the consummation of a change of control of the Company (as defined in the PHP Warrant) on or prior to November 15, 2028, all of the shares underlying the PHP Warrant would become immediately vested and exercisable; upon the consummation of a change of control of the Company after November 15, 2028 but on or prior to November 15, 2029, the shares underlying the second and third tranches of the PHP Warrant would become immediately vested and exercisable; and upon the consummation of a change of control of the Company after November 15, 2029 but on or prior to November 15, 2030, the shares underlying the third tranche of the PHP Warrant would become immediately vested and exercisable.

Refer to Note 12 for additional information on the PHP Warrant.

Clive Meanwell, M.D. and Tamsin Berry, members of the Company's board of directors, are Managing Partner and Partner of PHP, respectively.

9. Commitments and Contingencies

Operating Lease Commitments

In September 2021, the Company entered into a five-year noncancelable facilities lease agreement for approximately 9,600 square feet of office space in Waltham, Massachusetts. The monthly rental payments under the lease, which include base rent charges of $0.4 million per year, are subject to periodic rent increases through September 2026. In addition to base rent, monthly rental payments include the Company's proportionate share of operating expenses. The lease terms provide for one five-year extension term with base rent calculated on the then-market rate.

In June 2022, the Company entered into a two-year noncancelable agreement for dedicated laboratory and office space in Newton, Massachusetts (the "Newton, MA Lease"). The monthly rental payments under the agreement include base rent charges of $0.7 million per year. The agreement terms provide for a month-to-month extension after completion of the initial two-year term with base rent calculated on the then-market rate with three months' prior notice.

In September 2022, the Company amended the Newton, MA Lease. Pursuant to the amendment, the Company entered into a separate two-year noncancelable agreement for new dedicated laboratory and office space on the same campus as the Newton, MA Lease. The Company took occupancy of the new dedicated laboratory and office space in December 2022. The monthly rental payments under the amended agreement include base rent charges of $1.3 million per year. The agreement terms provide for a month-to-month extension, after completion of the initial two-year term extending through November 2024, with base rent calculated on the then-market rate with three months' prior notice.

The components of operating lease expense were as follows (in thousands):

	December 31, 2022
Lease cost:	
Operating lease cost	$ 754
Variable lease cost	31
Total lease cost	$ 785
Cash paid for amounts included in the measurement of lease liabilities:	
Operating cash flows related to operating leases	$ 837

Future minimum lease payments under the noncancelable leases as of December 31, 2022 was as follows (in thousands):

Year Ending December 31,	Operating Lease
2023	$ 1,731
2024	1,521
2025	430
2026	328
Total lease payments	4,010
Present value adjustment	(286)
Present value of operating lease liability	$ 3,724

As of December 31, 2022, the Company's operating lease was measured using a weighted-average incremental borrowing rate of 6.0% over a weighted-average remaining lease term of 2.6 years.

The total operating liability is presented on the Company's condensed consolidated balance sheet based on maturity dates. $1.5 million of the total operating liability is classified under "operating lease liability, current" for the portion due within twelve months, and $2.2 million is classified under "operating lease liability, non-current".

License Agreements

The Company has entered into license agreements with Adimab and WuXi Biologics (see Note 7).

Other Agreements

In November 2022, the Company entered into the PHP MSA (see Note 8). Concurrently with the PHP MSA, the Company entered into the PHP Work Order, pursuant to which PHP agreed to advise and counsel the Company regarding clinical development and regulatory matters with respect to its product candidates. The PHP Work Order is effective for six months from November 2022 and may be extended by written agreement of the Company and PHP. As compensation for the services and deliverables under the PHP Work Order, the Company is obligated to pay PHP a cash fee of $0.5 million per month during the term of the PHP Work Order for an Aggregate Fee of $3.0 million. In the event that (i) the Company terminates the PHP Work Order for any reason other than material breach by PHP or (ii) PHP terminates the PHP Work Order due to material breach by the Company, in each case, pursuant to the terms of the PHP MSA, the Company would be required to pay PHP the balance of the Aggregate Fee as of the date the PHP Work Order is terminated. The cash fee is subject to change if the parties extend the term of the PHP Work Order in accordance with the terms thereof.

Clinical and Manufacturing Agreements

In July 2020, the Company entered into a Clinical Master Services Agreement with WuXi Biologics (the "Clinical Master Services Agreement"). The Clinical Master Services Agreement outlines the terms and conditions under which WuXi Biologics coordinates biologics development and clinical manufacturing services for the Company.

In December 2020, the Company entered into a Commercial Manufacturing Services Agreement with WuXi Biologics, which was amended and restated in August 2021 (as amended and restated, the "Commercial Manufacturing Agreement"). The Commercial Manufacturing Agreement outlines the terms and conditions under which WuXi Biologics manufactures drug substance and drug product for commercial use.

The Company committed to minimum noncancelable purchase obligations related to batches of adintrevimab drug substance and certain services with respect to the product requirements for 2022 and 2023 and batches of adintrevimab drug product and certain services with respect to the product requirements for 2022, the payments for which will extend into 2023.

In April 2022, the total volume of contractually binding drug substance and drug product batches to be manufactured under the Commercial Manufacturing Agreement was reduced to $51.6 million, a decrease of $107.8 million from the previous commitment of minimum non-cancelable purchase obligations of $159.4 million. In addition, WuXi Biologics agreed to provide the Company with a credit in the low eight-figures to offset future services rendered by WuXi.

In July 2022, the Company provided notice to WuXi Biologics to cancel the contractually binding adintrevimab drug product batches.

In November 2022, WuXi Biologics reassigned the remaining contractually binding adintrevimab drug substance batches under the Commercial Manufacturing Agreement to contractually binding NVD200 drug substance batches under its Clinical Master Services Agreement. As of December 31, 2022, the total remaining cost of contractually binding NVD200 drug substance batches to be manufactured under the Clinical Master Services Agreement is $18.1 million, which is expected to be incurred and paid in 2023.

In March 2023, the remaining contractually binding batches were repurposed, and the related services now relate to manufacturing of VYD222.

During the year ended December 31, 2022, the majority of the low eight-figure credit was applied to WuXi Biologics services as a reduction of research and development expenses and a reduction of accounts payable and accrued expenses. The remaining portion of the credit is expected to be utilized during the first quarter of 2023.

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 enters into agreements with third parties in the ordinary course of business for various products and services, including those related to research, preclinical and clinical operations, manufacturing and support, supply chain, and distribution. These contracts do not contain any material minimum purchase commitments. Certain of these agreements provide for termination rights subject to the payment of termination fees and/or wind-down costs. Under such agreements, the Company is contractually obligated to make certain payments to vendors upon early termination, primarily to reimburse them for their unrecoverable outlays incurred prior to cancellation as well as any amounts owed by the Company prior to early termination. The actual amounts the Company could pay in the future to the vendors under such agreements may differ from the purchase order amounts due to cancellation provisions. The termination fees were not probable of payment as of December 31, 2022 and 2021.

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, 2022 and 2021, the Company was not a party to any material legal proceedings.

On January 31, 2023, a securities class action lawsuit captioned Brill v. Invivyd, Inc., et. al., Case No. 1:23-CV-10254-LTS, was filed against the Company and certain of its former officers in the U.S. District Court for the District of Massachusetts. The complaint alleges violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder on the basis of purportedly materially false and misleading statements and omissions concerning ADG20's effectiveness against the Omicron variant of COVID-19. The complaint seeks, among other things, unspecified damages, attorneys' fees, expert fees, and other costs.

The Company believes that is has strong defenses and it intends to vigorously defend against this action. The lawsuit is in early stages, and, at this time, no assessment can be made as to the likely outcome or whether the outcome will be material to the Company.

Additionally, the Company received a request from the SEC, dated March 22, 2023, for documents and information concerning, among other matters, the Company's testing and analysis of the efficacy of ADG20 against Omicron and other COVID-19 variants, its public statements regarding the potential use of ADG20 against the Omicron variant, and related communications with investors and the media. The Company intends to cooperate fully with this fact-finding inquiry.

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.

10. Convertible Preferred Stock

The Company has issued Series A convertible preferred stock (the "Series A Preferred Stock"), Series B convertible preferred stock (the "Series B Preferred Stock"), and Series C Preferred Stock (the "Series C Preferred Stock"), all of which are collectively referred to as the "Preferred Stock."

In July 2020, the Company issued and sold 6,237,500 shares of Series A Preferred Stock, at a price of $8.00 per share, for gross proceeds of $49.9 million and incurred $0.2 million of issuance costs. Concurrently, the Company issued 5,000,000 shares of Series A Preferred Stock to Adimab as consideration payable pursuant to the Adimab Assignment Agreement (see Note 7).

In October and November 2020, the Company issued and sold 1,410,434 shares of Series B Preferred Stock, at a price of $56.72 per share, for gross proceeds of $80.0 million and incurred $0.2 million of issuance costs. Adimab, a related party, participated in the Series B Preferred Stock financing by purchasing 44,076 shares of Series B Preferred Stock for an aggregate purchase price of $2.5 million. The issuance of the Series B Preferred Stock resulted in changes to certain terms of the Series A Preferred Stock. The Company concluded that such changes were not significant and resulted in a modification, rather than an extinguishment, of the Series A Preferred Stock. The changes to the terms of the Series A Preferred Stock did not result in incremental value to the stockholders. Therefore, there was no impact to the accounting for the Series A Preferred Stock.

In April 2021, the Company issued and sold 4,296,550 shares of its Series C Preferred Stock, at a price of $78.08578 per share, for aggregate gross proceeds of $335.5 million and incurred $0.3 million of issuance costs. Adimab, a related party, participated in the Series C Preferred Stock financing by purchasing 128,064 shares of Series C Preferred Stock for an aggregate purchase price of $10.0 million.

The terms of the Series C Preferred Stock were substantially the same as the terms of the Series A Preferred Stock and Series B Preferred Stock, except that the original issue price per share and the conversion price per share of the Series C Preferred Stock is $78.08578.

In July 2021, the Company filed an amended and restated certificate of incorporation, which increased the Company's authority to issue (i) 150,000,000 shares of common stock and (ii) 16,944,484 shares of Preferred Stock. In August 2021, in connection with the closing of the IPO, the Company filed an amended and restated certificate of incorporation to, among other things: (i) increase the number of authorized shares of common stock from 150,000,000 shares to 1,000,000,000 shares, (ii) eliminate all references to the previously existing series of convertible preferred stock and (iii) authorize 10,000,000 shares of undesignated preferred stock that may be issued from time to time by the Company's board of directors in one or more series.

Upon issuance of each series of Preferred Stock, the Company assessed the embedded conversion and liquidation features of the securities and determined that such features did not require the Company to separately account for these features. The Company also concluded that no beneficial conversion feature existed on the issuance date of each series of Preferred Stock.

Upon the closing of the Company's IPO in August 2021, all shares of the Company's convertible preferred stock then outstanding converted into 84,722,420 shares of common stock (see Note 11).

11. Common Stock

The voting, dividend and liquidation rights of the holders of shares of the Company's common stock were subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth above and described in the Company's final prospectus related to the IPO filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended (the "Securities Act") on August 6, 2021.

In June 2020, the Company issued and sold 21,250,000 shares of its common stock to Adimab upon formation of the Company for $0.00002 per share. In July 2020, such shares of common stock were repurchased by the Company from Adimab contemporaneous with the execution of the Adimab Assignment Agreement, pursuant to which the Company acquired certain intellectual property rights in exchange for the issuance of 5,000,000 shares of its Series A Preferred Stock. As of December 31, 2022 and 2021 the 21,250,000 shares of common stock repurchased from Adimab were retired and redesignated as authorized but unissued shares of the Company's common stock. The fair value of the repurchased common stock was $0.004 per share, or $85,000 in the aggregate, as determined based on a third-party valuation (see Note 7).

In April 2021, the Company increased the number of shares of common stock authorized for issuance from 19,000,000 to 23,251,555 shares and increased the number of shares of preferred stock authorized for issuance from 12,647,934 to 16,944,484 shares, of which 4,296,550 shares were designated as Series C Preferred Stock.

As described in Note 10 above, in July 2021, the Company filed an amended and restated certificate of incorporation, which increased the Company's authority to issue 150,000,000 shares of common stock. In August 2021, in connection with the closing of the IPO, the Company filed an amended and restated certificate of incorporation to, among other things, increase the number of authorized shares of common stock from 150,000,000 shares to 1,000,000,000 shares.

As of December 31, 2022, the Company had reserved 44,164,654 shares of common stock for the exercise of outstanding stock options and the issuance of awards available for grant under the Company's 2020 Equity Incentive Plan, 2021 Equity Incentive Plan and 2021 Employee Stock Purchase Plan (see Note 12).

Shelf Registration Statement

In September 2022, the Company filed a shelf registration statement on Form S-3 with the SEC (File No. 333-267643) and accompanying base prospectus, which was declared effective by the SEC on October 5, 2022, for the offer and sale of up to $400 million of the Company's securities.

Treasury Stock

In April and May 2021, the Company retired an aggregate of 22,600,000 shares of common stock held in treasury. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

In November 2021, the Company repurchased 468,751 shares of unvested restricted common stock at the original purchase price upon a termination of service during the vesting period. As of December 31, 2021, the shares of common stock repurchased were recorded as treasury stock in the accompanying consolidated balance sheets and consolidated statements of convertible preferred stock and stockholders' equity (deficit) as such shares were not retired. The fair value of the repurchased common stock was insignificant.

In February and June 2022, the Company repurchased 1,158,089 and 992,648 shares of unvested restricted common stock, respectively, at the original purchase price upon a termination of service during the vesting period. The shares of common stock repurchased were recorded as treasury stock in the accompanying condensed consolidated balance sheets and consolidated statements of convertible preferred stock and stockholders' equity (deficit) as such shares were not retired. The fair value of the repurchased common stock was insignificant.

In March and September 2022, the Company retired an aggregate of 1,626,840 and 992,648 shares of common stock, respectively, held in treasury. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

In March 2023, the Company repurchased 206,802 shares of unvested restricted common stock at the original purchase price upon a termination of service during the vesting period.

Stock Split

In July 2021, the Company effected a five-for-one stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios of each series of the Company's preferred stock (see Note 10). Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this stock split and adjustment of the Preferred Stock conversion ratios.

Initial Public Offering

In August 2021, the Company completed its IPO, pursuant to which it issued and sold 20,930,000 shares of its common stock at an initial public offering price of $17.00 per share, including 2,730,000 shares of its common stock pursuant to the full exercise of the underwriters' option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were approximately $327.5 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all of the shares of the Company's convertible preferred stock then outstanding converted into 84,722,420 shares of common stock. Upon the conversion of the convertible preferred stock, the Company reclassified the carrying value of the convertible preferred stock to common stock (at par value) and additional paid-in capital.

12. Stock-Based Compensation

2020 Equity Incentive Plan

The Company's 2020 Equity Incentive Plan (the "2020 Plan") provides for the Company to grant incentive stock options, non-qualified stock options, restricted stock awards, restricted stock units and other stock-based awards to employees, members of the board of directors and consultants. The 2020 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The board of directors may also delegate to one or more officers of the Company the power to grant awards to employees and certain officers of the Company. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee or any such officer if so delegated.

The exercise price for stock options granted may not be less than the fair market value of the Company's common stock on the date of grant, as determined by the board of directors, or at least 110% of the fair market value of the Company's common stock on the date of grant in the case of an incentive stock option granted to an employee who owns stock representing more than 10% of the voting power of all classes of stock as determined by the board of directors as of the date of grant. Prior to the IPO, the Company's board of directors determined the fair value of the Company's common stock, taking into consideration its most recently available valuation of common stock performed by third parties as well as additional factors which may have changed since the date of the most recent contemporaneous valuation through the date of grant. Stock options granted under the 2020 Plan expire after ten years and typically vest over a four-year period with the first 25% vesting upon the first anniversary of a specified vesting commencement date and the remainder vesting in 36 equal monthly installments over the succeeding three years, contingent on the recipient's continued employment or service. Certain awards of stock options permit the holders to exercise the option in whole or in part prior to the full vesting of the option in exchange for unvested shares of restricted common stock with respect to any unvested portion of the option so exercised.

As of December 31, 2022, there were 10,362,687 shares authorized to be issued upon the exercise of outstanding stock option grants and no shares reserved for future issuance under the 2020 Plan.

2021 Equity Incentive Plan

In July 2021, the Company's board of directors adopted, and its stockholders approved, the 2021 Equity Incentive Plan (the "2021 Plan"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. The 2021 Plan provides for the grant of incentive stock options, non-statutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares reserved for issuance under the 2021 Plan was equal to 35,075,122, which is the sum of 11,413,572 new shares; plus the number of shares (not to exceed 23,661,550 shares), which represents (i) the number of shares that remained available for issuance under the 2020 Plan, at the time the 2021 Plan became effective, and (ii) any shares subject to outstanding stock options or other stock awards that were granted under the 2020 Plan that are forfeited, terminate, expire or are otherwise not issued. In addition, the number of shares of the Company's common stock reserved for issuance under the 2021 Plan will

automatically increase on the first day of each calendar year, beginning on January 1, 2022 and continuing through January 1, 2031, in an amount equal to 5% of the shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, or a lesser number of shares determined by the board of directors. On January 1, 2022, 5,539,145 shares of common stock were automatically added to the shares authorized for issuance under the 2021 Plan. The number of shares to be issued under the 2021 Plan did not increase on January 1, 2023 as determined by the Company's 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.

As of December 31, 2022, there were an aggregate of 42,935,402 shares authorized to be issued under the 2020 Plan and the 2021 Plan, which includes 10,362,687 and 12,876,704 shares authorized to be issued upon the exercise of outstanding stock option grants from the 2020 Plan and 2021 Plan, respectively, and 0 and 19,696,011 shares reserved for future issuance under the 2020 Plan and 2021 Plan, respectively.

Stock Option Valuation

The fair value of stock option grants is estimated using the Black-Scholes option-pricing model. Prior to its IPO in August 2021, the Company had been a private company. Due to the proximity to the IPO, the Company continues to lack sufficient company-specific historical and implied volatility information. Therefore, it estimates its expected stock volatility based on the historical volatility of a publicly traded set of peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. For options with service-based vesting conditions, the expected term of the Company's stock options has been determined utilizing the "simplified" method. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table presents, on a weighted-average basis, the assumptions used in the Black-Scholes option-pricing model to determine the grant-date fair value of stock options granted:

	2022	2021
Expected term (in years)	6.0	6.0
Expected volatility	71.8%	73.3%
Risk-free interest rate	2.7%	1.0%
Expected dividend yield	—%	—%

Stock Option Activity

The following table summarizes the Company's stock option activity since December 31, 2021:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	18,871,592	$ 10.15	9.3	$ 24,897
Granted	12,625,109	4.30		
Exercised	(298,353)	0.81		
Forfeited	(7,958,957)	10.41		
Outstanding at December 31, 2022	23,239,391	$ 7.01	7.9	$ 1,594
Vested and expected to vest at December 31, 2022	23,239,391	$ 7.01	7.9	$ 1,594
Options exercisable at December 31, 2022	6,845,330	$ 8.25	6.3	$ 1,001

The weighted-average grant date fair value of stock options granted during the year ended December 31, 2022 and 2021 was $2.79 and $7.56, respectively, per share.

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair market value of the common stock for the options that had exercise prices lower than the estimated fair value of the Company's common stock at December 31, 2022 and December 31, 2021.

The total intrinsic value of stock options exercised was $1.0 million for the year ended December 31, 2022. There were no options exercised during the year ended December 31, 2021.

In July 2022, David Hering, M.B.A. was appointed as the Company's Chief Executive Officer. In conjunction with this appointment, Mr. Hering was granted a stock option to purchase 2,000,000 shares of common stock, which vest monthly in equal installments over 48 months.

Mr. Hering was also eligible to receive an additional stock option to purchase up to 1,000,000 shares of common stock (the "Additional Option Grant") if certain goals approved by the Company's board of directors, on the recommendation of the Compensation Committee, were achieved on or prior to December 31, 2022, with such achievement to be determined by the Company's board of directors, upon the recommendation of the Compensation Committee. If such performance goals were partially achieved on or prior to December 31, 2022, then Mr. Hering was entitled to receive a partial amount of the Additional Option Grant, with such partial amount to be determined by the Company's board of directors, in its sole and absolute discretion. In December 2022, Mr. Hering received a partial amount of the Additional Option Grant and was granted a stock option to purchase 700,000 shares of common stock, which vests in monthly equal installments over a 48-month period commencing on the grant date.

Early Exercise of Stock Options into Restricted Stock

The Company's restricted stock activity during the year ended December 31, 2022 was solely due to shares of restricted common stock issued pursuant to the permitted early exercise of stock options as permitted under the 2020 Plan prior to amendments. The 2021 Plan does not permit early exercise of stock options. Shares of common stock issued upon exercise of unvested stock options are restricted and continue to vest in accordance with the original vesting schedule applicable to the associated stock option award. The Company has the right to repurchase any unvested shares of restricted common stock, at the original purchase price, upon any voluntary or involuntary termination of the service relationship during the vesting period.

	Number of Shares
Unvested restricted stock at December 31, 2021	3,082,175
Issued	—
Vested	(571,105)
Repurchased	(2,150,737)
Unvested restricted stock at December 31, 2022	360,333

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 each of December 31, 2022 and 2021, the liability related to the payments for unvested shares from early-exercised options was less than $0.1 million.

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):

	2022	2021
Research and development	$ 12,800	$ 6,591
Selling, general and administrative	8,848	11,173
	$ 21,648	$ 17,764

In February 2022, Tillman U. Gerngross, Ph.D., resigned as Chief Executive Officer and President and as a member of the Company's board of directors. In accordance with his resignation, Dr. Gerngross's outstanding stock options were forfeited, resulting in a reversal of selling, general and administrative related stock-based compensation expense of approximately $4.6 million.

As of December 31, 2022, total unrecognized stock-based compensation cost related to unvested awards was $62.0 million and the weighted-average period over which such expense is expected to be recognized was 2.8 years.

2021 Employee Stock Purchase Plan

In July 2021, the Company's board of directors adopted, and its stockholders approved, the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective immediately prior to and contingent upon the execution of the underwriting agreement related to the Company's IPO. A total of 1,342,773 shares of common stock were initially reserved for issuance under the 2021 ESPP. There were 113,521 shares issued under the 2021 ESPP as of December 31, 2022. The number of shares of common stock that may be issued under the 2021 ESPP will automatically increase on the first day of each calendar year, beginning on January 1, 2022 and continuing through January 1, 2031, by an amount equal to the lesser of (i) 1% of the shares of common stock outstanding on the last day of the calendar month before the date of each automatic increase, (ii) 2,685,546 shares and (iii) an amount determined by the Company's board of directors. The number of shares to be issued under the 2021 ESPP did not increase on January 1, 2023 as determined by the Company's board of directors. The first offering under the 2021 ESPP was June 6, 2022. As of December 31, 2022, 1,229,252 shares remained available for issuance under the 2021 ESPP. During the year ended December 31, 2022, the Company recognized $0.1 million in related stock-based compensation expense.

Warrant Expense

In November 2022, the Company entered into the PHP MSA, the PHP Work Order and a warrant agreement with respect to the PHP Warrant. To compensate for the services and deliverables provided by PHP, the Company issued 6,824,712 equity-classified warrants to PHP. Each warrant shall give the right to acquire common stock of the Company at a purchase price of $3.48 per share. Per the agreement, the PHP Warrant is exercisable upon either the achievement of corresponding market capitalization targets or a consummation of a fundamental transaction (as defined in the PHP Warrant); as such, there are no other requirements, including any continuous service requirements, in order for PHP to be entitled to the PHP Warrant, if and when any portion of it vests.

The following table sets forth the activity relating to the PHP Warrant outstanding for the year ended December 31, 2022 (aggregate value in thousands):

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	—	$ —	—	$ —
Granted	6,824,712	3.48		
Outstanding at December 31, 2022	6,824,712	$ 3.48	9.88	$ —
Warrants exercisable at December 31, 2022	—	$ —	—	$ —

Assumptions used to determine the fair value of PHP Warrant using the simulation model based on Geometric Brownian Motion in a risk-neutral framework are as follows:

	Year Ended December 31, 2022
Weighted-average grant date fair value per warrant	$ 2.55
Expected term (in years)	10.0
Expected volatility	70.0%
Risk-free interest rate	3.8%
Expected dividend yield	—%
Common shares outstanding	108,982,401

The aggregate grant date fair value of the PHP Warrant was $17.4 million which was recognized as warrant expense on the grant date.

13. Income Taxes

During the years ended December 31, 2022 and 2021, the Company did not record income tax benefits for the net operating losses ("NOLs") 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 U.S.

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	2022	2021
Federal statutory income tax rate	(21.0)%	(21.0)%
State income taxes, net of federal benefit	(3.5)	(2.9)
Federal research and development tax credits	(4.1)	(1.4)
Stock-based compensation	0.3	—
Change in deferred tax asset valuation allowance	28.3	25.3
Effective income tax rate	—%	—%

The Company's net deferred tax assets consisted of the following (in thousands):

	Year Ended December 31,	
	2022	2021
Deferred tax assets:		
Net operating loss carryforwards	$ 61,653	$ 51,635
Capitalized research and development	36,550	—
Research and development tax credit carryforwards	16,901	4,350
Stock-based compensation expense	8,308	4,116
Warrant expense	4,066	—
Intangibles	2,602	1,707
Operating lease liability	871	—
Other	1,269	1,160
Total gross deferred tax assets	132,220	62,968
Valuation allowance	(131,325)	(62,968)
Total deferred tax assets	$ 895	$ —
Deferred tax liabilities:		
Operating lease right-of-use assets	$ (884)	$ —
Depreciation expense	(11)	—
Total deferred tax liabilities	(895)	—
Total net deferred tax assets	$ —	$ —

As of December 31, 2022 and 2021, the Company had U.S. federal NOL carryforwards of $263.7 million and $221.9 million, respectively, which may be available to reduce future taxable income. All of the U.S. federal NOL carryforwards have an indefinite carryforward period but are limited in their usage to 80% of annual taxable income. In addition, as of December 31, 2022, the Company had state NOL carryforwards of $103.3 million, which may be available to reduce future taxable income, of which $7.0 million have an indefinite carryforward period while the remaining $96.3 million begin to expire in 2032. As of December 31, 2022, the Company also had U.S. federal and state research and development tax credit carryforwards of $13.2 million and $3.6 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2041 and 2036, respectively.

Utilization of the U.S. federal and state NOL carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income or tax liabilities. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the NOL carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. If a change in ownership were to have occurred during that period and resulted in the restriction of NOL or credit carryforwards, the reduction in the related deferred tax asset would be offset with a corresponding reduction in the valuation allowance.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative losses since inception, expectation of future losses and lack

of other positive evidence and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2022 and 2021. Management reevaluates the positive and negative evidence at each reporting period. During the years ended December 31, 2022 and 2021, the Company increased its valuation allowance by $68.3 million and $57.3 million, respectively, with such increase recognized as income tax expense, in order to maintain a full valuation allowance against its deferred tax assets, and there were no changes recorded to the allowance during the period.

The Company assesses uncertain tax positions in accordance with the guidance for accounting for uncertain tax positions. This pronouncement prescribes a recognition threshold and measurement methodology for recording within the consolidated financial statements uncertain tax positions taken, or expected to be taken, in the Company's income tax returns. To the extent the uncertain tax positions do not meet the "more likely than not" threshold, the Company derecognizes such positions. For tax positions meeting the "more likely than not" threshold, the Company measures and records the highest probable benefit, and establishes appropriate reserves for benefits that exceed the amount likely to be sustained upon examination. As of December 31, 2022 and 2021, the Company has not recorded any uncertain tax positions or related interest and penalties.

The Company files income tax returns in the U.S. federal and various state jurisdictions and is not currently under examination by any taxing authority for any open tax year. Due to NOL carryforwards, all years remain open for income tax examination. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the federal or state tax authorities to the extent utilized in a future period. No federal or state tax audits are currently in process.

14. 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, as amended, that covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. Pursuant to the terms of the 401(k) Plan, the Company is required to make non-elective contributions of 3% of eligible participants' compensation. For the years ended December 31, 2022 and 2021, the Company contributed $0.8 million and $0.6 million, respectively, to the 401(k) Plan.

15. 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):

	2022	2021
Numerator:		
Net loss attributable to common stockholders	$ (241,317)	$ (226,790)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	108,268,289	42,621,265
Net loss per share attributable to common stockholders, basic and diluted	$ (2.23)	$ (5.32)

Shares of unvested restricted common stock are not considered outstanding for accounting purposes until vested and were excluded from the calculations of basic net loss per share attributable to common stockholders for all periods presented.

The Company's potential dilutive securities have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same. The Company excluded the following potential common shares, presented based on amounts outstanding at each period end, from the computation of diluted net loss per share attributable to common stockholders for the periods indicated, because including them would have had an anti-dilutive effect:

	2022	2021
Stock options to purchase common stock	23,239,391	18,871,592
Unvested restricted common stock	360,333	3,082,175
Warrants to purchase common stock	6,824,712	—
	30,424,436	21,953,767

16. Related Party Transactions

Adimab participated in the Series B Preferred Stock financing and the Series C Preferred Stock financing by purchasing 44,076 and 128,064 shares of Series B Preferred Stock and Series C Preferred Stock, respectively, for an aggregate purchase price of $2.5 million and $10.0 million, respectively (see Note 10).

Adimab Assignment Agreement

Under the Adimab Assignment Agreement, Adimab, a principal stockholder of the Company, received upfront consideration in the form of Series A Preferred Stock, is entitled to receive milestone and royalty payments upon specified conditions, and receives payments from the Company for providing ongoing services under the agreement (see Note 7).

The Company did not recognize any IPR&D expense in connection with milestones payable during the year ended December 31, 2022. During the year ended December 31, 2021, the Company recognized $7.5 million as IPR&D expense in connection with milestones payable.

During the years ended December 31, 2022 and 2021, the Company recognized $0.6 million and $1.3 million, respectively, of research and development expense with respect to services performed by Adimab on the Company’s behalf.

Adimab Collaboration Agreement

Under the Adimab Collaboration Agreement, the Company is obligated to pay Adimab for certain fees, milestone and royalty payments (see Note 7).

During the years ended December 31, 2022 and 2021, the Company recognized $5.2 million and $2.6 million, respectively, of research and development expense related to the quarterly fee.

During the years ended December 31, 2022 and 2021, the Company recognized $1.7 million and $0.3 million, respectively, of research and development expense with respect to services performed by Adimab on the Company’s behalf.

During the year ended December 31, 2022, the Company recognized $1.0 million of IPR&D expense related to an option exercise fee. The Company did not recognize any IPR&D expense related to an option exercise fee during the year ended December 31, 2021.

During the year ended December 31, 2022, the Company recognized $0.4 million of IPR&D expense related to drug delivery fees. The Company did not recognize any IPR&D expense related to drug delivery fees during the year ended December 31, 2021.

Adimab Platform Transfer Agreement

Under the Adimab Platform Transfer Agreement, the Company is obligated to pay Adimab for certain fees, milestone and royalty payments (see Note 7).

During the year ended December 31, 2022, the Company recognized $3.0 million of IPR&D expense in connection with the upfront consideration payable for the rights assigned pursuant to the Adimab Platform Transfer Agreement. The Adimab Platform Transfer Agreement was not in effect during the year ended December 31, 2021.

As of December 31, 2022 and 2021, $0.3 million and $0.6 million, respectively, was due to Adimab under the Adimab Assignment Agreement, the Adimab Collaboration Agreement and the Adimab Platform Transfer Agreement by the Company. As of December 31, 2022 and 2021, no amounts were due from Adimab under the Adimab Assignment Agreement, the Adimab Collaboration Agreement or the Adimab Platform Transfer Agreement to the Company.

Mithril Group

In March 2022, a group of stockholders, including, among others, Adimab; Mithril II LP; M28 Capital Management LP; Polaris Venture Partners V, L.P.; and Population Health Equity Partners III, L.P., which are collectively referred to as the Mithril Group, submitted a notice of intent to nominate three directors to the Company’s board of directors at the 2022 annual meeting of stockholders. In April 2022, the Mithril Group filed definitive proxy materials with the SEC seeking election of three directors to the Company's board of directors and adoption of a non-binding resolution for director declassification.

Subsequently, during the year ended December 31, 2022, Mithril II LP requested that the Company reimburse it for costs associated with legal expenses, corporate governance matters and stockholder proposals incurred as a result of the aforementioned matters in connection with the Company’s 2022 annual meeting of stockholders. The Company made such

reimbursement payment to Mithril II LP in the amount of $1.4 million, which the Company recognized as a selling, general and administrative expense.

As of December 31, 2022, no amounts were due to any member of the Mithril Group by the Company, and no amounts were due from any member of the Mithril Group to the Company.

Population Health Partners, L.P.

Under the PHP MSA and PHP Work Order, the Company is obligated to pay cash compensation for services and deliverables (see Note 8). Clive Meanwell, M.D. and Tamsin Berry, members of the Company's board of directors, are Managing Partner and Partner of PHP, respectively.

During the year ended December 31, 2022, the Company recognized $0.8 million of research and development expense related to services performed by PHP in connection with the PHP Work Order.

During the year ended December 31, 2022, the Company recognized $17.4 million of warrant expense related to warrants issued to PHP in connection with the PHP Warrant.

As of December 31, 2022, $0.8 million was due to PHP by the Company, and no amounts were due from PHP to the Company.

The agreements with PHP were not in effect during the year ended December 31, 2021.

Exhibit 4.2

DESCRIPTION OF INVIVYD, INC. COMMON STOCK

The following description of the common stock of Invivyd, Inc., or the Company, and certain provisions of the Company's amended and restated certificate of incorporation, or the Restated Certificate, and amended and restated bylaws, or the Bylaws, are summaries. These summaries are qualified in their entirety by reference to the provisions of the General Corporation Law of the State of Delaware and the complete texts of the Restated Certificate, the Certificate of Amendment to the Restated Certificate, and the Bylaws, which are incorporated by reference as Exhibits 3.1, 3.2, and 3.3, respectively, of the Company's Annual Report on Form 10-K to which this description is also an exhibit.

General

The Restated Certificate authorizes the Company to issue up to 1,000,000,000 shares of common stock, $0.0001 par value per share, and 10,000,000 shares of preferred stock, $0.0001 par value per share, all of which shares of preferred stock are undesignated. The Company's board of directors may establish the rights and preferences of the preferred stock from time to time.

Common Stock

Voting Rights

Each holder of the Company's common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. The affirmative vote of holders of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, is required to amend certain provisions of the Restated Certificate, including provisions relating to amending the Company's Bylaws, the classified board, the size of the Company's board, removal of directors, director liability, vacancies on the Company's board, special meetings, stockholder notices, actions by written consent and exclusive forum.

Dividends

Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of common stock are entitled to receive ratably those dividends, if any, as may be declared from time to time by the board of directors out of legally available funds.

Liquidation

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

Rights and Preferences

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

Anti-Takeover Provisions

Section 203 of the Delaware General Corporation Law

The Company is subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least eighty-five percent (85%) of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least sixty-six and two-thirds percent (66 2/3%) of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a “business combination” to include the following:

- any merger or consolidation involving the corporation or any direct or indirect majority-owned subsidiary of the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, pledge, transfer or other disposition of ten percent (10%) or more of the assets of the corporation or of any direct or indirect majority-owned subsidiary involving the interested stockholder (in one transaction or a series of transactions);
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation or by any direct or indirect majority-owned subsidiary of the corporation of any stock of the corporation or of such subsidiary to the interested stockholder;
- any transaction involving the corporation or any direct or indirect majority-owned subsidiary of the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation or any such subsidiary beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation or any direct or indirect majority-owned subsidiary.

In general, Section 203 defines an “interested stockholder” as an entity or person who, together with the person’s affiliates and associates, beneficially owns, or within three years prior to the time of determination of interested stockholder status did own, fifteen percent (15%) or more of the outstanding voting stock of the corporation.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

The Restated Certificate and the Bylaws provide for the Company’s board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of the Company’s stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because the Company’s stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding are able to elect all of the Company’s directors. The Restated Certificate and the Bylaws provide that directors may be removed by the stockholders only for cause upon the vote of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then-outstanding shares of capital stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board and subject to the rights of any series of then-outstanding Preferred Stock, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

The Restated Certificate and the Bylaws also provide that all stockholder actions must be effected at a duly called meeting of stockholders and eliminate the right of stockholders to act by written consent without a meeting. The Bylaws provide that only the chairman of the board of directors, the chief executive officer or the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors may call a special meeting of stockholders.

The Bylaws also provide that stockholders seeking to present proposals before a meeting of stockholders to nominate candidates for election as directors at a meeting of stockholders must provide timely advance notice in writing and specify requirements as to the form and content of a stockholder's notice.

The Restated Certificate and the Bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of at least sixty-six and two-thirds percent (66 2/3%) of the voting power of all of the then-outstanding shares of capital stock.

The Restated Certificate gives the Company's board of directors the authority, without further action by the Company's stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control.

The combination of these provisions makes it more difficult for the Company's existing stockholders to replace the Company's board of directors as well as for another party to obtain control of the Company by replacing the Company's board of directors. Since the Company's board of directors has the power to retain and discharge the Company's officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for the Company's board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of the Company.

These provisions are intended to enhance the likelihood of continued stability in the composition of the Company's board of directors and its policies and to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to reduce the Company's vulnerability to hostile takeovers and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for the Company's shares and may have the effect of delaying changes in the Company's control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of the Company's stock that could result from actual or rumored takeover attempts. The Company believes that the benefits of these provisions, including increased protection of the Company's potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure the Company's company, outweigh the disadvantages of discouraging takeover proposals, because negotiation of takeover proposals could result in an improvement of their terms.

Exhibit 4.3

EXECUTION VERSION

NEITHER THIS WARRANT NOR THE SECURITIES FOR WHICH THIS WARRANT IS EXERCISABLE HAVE BEEN REGISTERED WITH THE SECURITIES AND EXCHANGE COMMISSION OR THE SECURITIES COMMISSION OF ANY STATE IN RELIANCE UPON AN EXEMPTION FROM REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), AND, ACCORDINGLY, MAY NOT BE OFFERED OR SOLD EXCEPT PURSUANT TO AN EFFECTIVE REGISTRATION STATEMENT UNDER THE SECURITIES ACT OR PURSUANT TO AN AVAILABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE SECURITIES ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS, AND IN THE CASE OF A TRANSACTION EXEMPT FROM REGISTRATION, UNLESS SOLD PURSUANT TO RULE 144 UNDER THE SECURITIES ACT OR THE COMPANY HAS RECEIVED DOCUMENTATION REASONABLY SATISFACTORY TO IT THAT SUCH TRANSACTION DOES NOT REQUIRE REGISTRATION UNDER THE SECURITIES ACT.

COMMON STOCK PURCHASE WARRANT

INVIVYD, INC.

First Tranche Shares: 3,591,954
Second Tranche Shares: 1,795,977
Third Tranche Shares: 1,436,781

THIS COMMON STOCK PURCHASE WARRANT (this "Warrant") certifies that, for value received, Population Health Partners, L.P., a Delaware limited partnership (the "Holder"), is entitled, upon the terms and subject to the limitations on exercise and the conditions hereinafter set forth, at any time on or after the Applicable Issuance Date (as defined herein) with respect to the Applicable Warrant Shares (as defined below) and on or prior to the earlier of (i) 5:00 p.m. (New York City time) on November 15, 2032 and (ii) the closing of a Fundamental Transaction in accordance with Section 3(d)(ii) (such earlier date, the "Termination Date"), but not thereafter, to subscribe for and purchase from Invivyd, Inc., a Delaware corporation (the "Company"), the Applicable Warrant Shares that become exercisable pursuant to the terms of this Warrant. The purchase price of one share of Common Stock under this Warrant shall be equal to the Exercise Price, as defined in Section 2(c).

Section 1.Definitions. In addition to the terms defined elsewhere in this Warrant, for all purposes of this Warrant, the following terms have the meanings set forth in this Section 1:

"Affiliate" means, with respect to any Person, any other Person directly or indirectly controlling, controlled by, or under common control with such Person as of the date on which, or at any time during the period for which, the determination of affiliation is being made (for purposes of this definition, the term "control" (including the correlative meanings of the terms "controlled by" and "under common control with"), as used with respect to any Person, means the

possession, direct or indirect, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of voting securities, by contract or otherwise). For purposes of this Agreement, the Company shall not be deemed to be an Affiliate of Holder and Holder shall not be deemed to be an Affiliate of the Company.

"Applicable Issuance Date" means, as applicable, (i) the First Tranche Issuance Date with respect to the First Tranche Shares, (ii) the Second Tranche Issuance Date with respect to the Second Tranche Shares, and (iii) the Third Tranche Issuance Date with respect to the Third Tranche Shares.

"Applicable Issuance Deadline" means, as applicable, the First Tranche Issuance Deadline, the Second Tranche Issuance Deadline and the Third Tranche Issuance Deadline.

"Applicable Issuance Event" means, as applicable, the First Tranche Issuance Event, the Second Tranche Issuance Event and the Third Tranche Issuance Event.

"Applicable Warrant Shares" means, as applicable, the First Tranche Shares, the Second Tranche Shares and the Third Tranche Shares.

"Business Day" means any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States or any day on which banking institutions in the State of New York are authorized or required by law or other governmental action to remain closed.

"Commission" means the U.S. Securities and Exchange Commission.

"Common Stock" means the common stock of the Company, par value $0.0001 per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Common Stock Equivalents" means any securities of the Company or its Subsidiaries which would entitle the holder thereof to acquire at any time Common Stock, including, without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Stock.

"Determination Date" has the meaning set forth in the definition of Market Capitalization.

" Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"First Tranche Issuance Date" means the first date on which the First Tranche Issuance Event occurs so long as the First Tranche Issuance Event occurs on or prior to the First Tranche Issuance Deadline.

"First Tranche Issuance Deadline" means November 15, 2028.

"First Tranche Issuance Event" means the Company's Market Capitalization as of any Determination Date equals or exceeds $758,517,511.00; provided, however, that, without regard to the Company's Market Capitalization, the First Tranche Issuance Event shall be deemed to occur immediately prior to the consummation of a Fundamental Transaction if such Fundamental Transaction occurs on or prior to the First Tranche Issuance Deadline.

"First Tranche Shares" means 3,591,954 shares of Common Stock, subject to applicable adjustment hereunder.

"Fundamental Transaction" means each of the following events: (a) other than in the case of a redomestication transaction in connection with a change in the corporate domicile of the Company, the Company, directly or indirectly, in one or more related transactions effects any merger or consolidation of the Company with or into another Person and the Company shall not be the surviving or continuing Person or the Company shall be the continuing or surviving Person but, in connection with such merger or consolidation, the Common Stock shall be changed into or exchanged for stock or other securities of any other Person or cash or any other property, (b) the Company, directly or indirectly, effects any sale, exclusive lease, exclusive license, assignment, transfer, conveyance or other disposition of all or substantially all of its assets in one or a series of related transactions, (c) any, direct or indirect, purchase offer, tender offer or exchange offer (whether by the Company or another Person) is completed pursuant to which holders of Common Stock are permitted to sell, tender or exchange their shares for other securities, cash or property and has been accepted by the holders of 50% or more of the outstanding Common Stock, (d) the Company, directly or indirectly, in one or more related transactions effects any compulsory share exchange pursuant to which the Common Stock is effectively converted into or exchanged for other securities, cash or property or (e) the Company, directly or indirectly, in one or more related transactions consummates a stock or share purchase agreement or other business combination (including, without limitation, a reorganization, recapitalization, spin-off or scheme of arrangement) with another Person or group of Persons whereby such other Person or group acquires more than 50% of the outstanding shares of Common Stock.

"Market Capitalization" means, with respect to a particular Trading Day (the "Determination Date"), the total value of the Company's outstanding shares of Common Stock on such Determination Date, calculated by multiplying the Company's VWAP for the ten (10) Trading Days immediately preceding the Determination Date by the Company's total number of shares of Common Stock outstanding as reflected in (i) the Company's most recent periodic or annual report filed with the Commission (e.g., Annual Report on Form 10-K or Quarterly Report on Form 10-Q), as the case may be, (ii) a more recent public announcement by the Company or (iii) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Second Tranche Issuance Date" means the first date on which the Second Tranche Issuance Event occurs so long as the Second Tranche Issuance Event occurs on or prior to the Second Tranche Issuance Deadline.

"Second Tranche Issuance Deadline" means November 15, 2029.

"Second Tranche Issuance Event" means the Company's Market Capitalization as of any Determination Date equals or exceeds $1,137,776,266.00; provided, however, that, without regard to the Company's Market Capitalization, the Second Tranche Issuance Event shall be deemed to occur immediately prior to the consummation of a Fundamental Transaction if such Fundamental Transaction occurs on or prior to the Second Tranche Issuance Deadline.

"Second Tranche Shares" means 1,795,977 shares of Common Stock, subject to applicable adjustment hereunder.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Standard Settlement Period" means the standard settlement period, expressed in a number of Trading Days, on the Company's primary Trading Market with respect to the Common Stock as in effect on the date of delivery of the Notice of Exercise.

"Subsidiary" or "Subsidiaries" means any subsidiary of the Company, and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Third Tranche Issuance Date" means the first date on which the Third Tranche Issuance Event occurs so long as the Third Tranche Issuance Event occurs on or prior to the Third Tranche Issuance Deadline.

"Third Tranche Issuance Deadline" means November 15, 2030.

"Third Tranche Issuance Event" means the Company's Market Capitalization as of any Determination Date equals or exceeds $1,517,035,022.00; provided, however, that, without regard to the Company's Market Capitalization, the Third Tranche Issuance Event shall be deemed to occur immediately prior to the consummation of a Fundamental Transaction if such Fundamental Transaction occurs on or prior to the Third Tranche Issuance Deadline.

"Third Tranche Shares" means 1,436,781 shares of Common Stock, subject to applicable adjustment hereunder.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which the Common Stock is listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, the New York Stock Exchange or the OTC Bulletin Board (or any successors to any of the foregoing).

"Transfer Agent" means American Stock Transfer & Trust Company, LLC., the current transfer agent of the Company, with a mailing address of 6201 15th Avenue, Brooklyn,

New York 11219, and a facsimile number of 718-765-8717, and any successor transfer agent of the Company.

"VWAP" means, for any date, the price determined by the first of the following clauses that applies: (a) if the Common Stock is then listed or quoted on a Trading Market, the daily volume weighted average price of the Common Stock for such date (or the nearest preceding date) on the Trading Market on which the Common Stock is then listed or quoted as reported by Bloomberg L.P. (based on a Trading Day from 9:30 a.m. (New York City time) to 4:02 p.m. (New York City time)), (b) if OTCQB or OTCQX is not a Trading Market, the volume weighted average price of the Common Stock for such date (or the nearest preceding date) on OTCQB or OTCQX as applicable, (c) if the Common Stock is not then listed or quoted for trading on OTCQB or OTCQX and if prices for the Common Stock are then reported in the "Pink Sheets" published by OTC Markets Group, Inc. (or a similar organization or agency succeeding to its functions of reporting prices), the most recent bid price per share of the Common Stock so reported, or (d) in all other cases, the fair market value of a share of Common Stock as determined in good faith by the Board of Directors, whose determination shall be conclusive.

Section 2.Exercise.

(a) Exercise Period. The Warrant is exercisable, in whole or in part, in three tranches commencing on the Applicable Issuance Date for the Applicable Warrant Shares and ending on the Termination Date. Promptly upon the occurrence of an Applicable Issuance Event (but in no event later than five (5) Trading Days following the occurrence of an Applicable Issuance Event), the Company shall deliver to the Holder a notice which shall detail the date on which such Applicable Issuance Event has occurred and the aggregate number of Applicable Warrant Shares then exercisable under the terms of this Warrant. For the avoidance of doubt, (i) the First Tranche Shares shall only become exercisable if the First Tranche Issuance Event occurs on or prior to the First Tranche Issuance Deadline, (ii) the Second Tranche Shares shall only become exercisable if the Second Tranche Issuance Event occurs on or prior to the Second Tranche Issuance Deadline, and (iii) the Third Tranche Shares shall only become exercisable if the Third Tranche Issuance Event occurs on or prior to the Third Tranche Issuance Deadline. If an Applicable Issuance Event does not occur on or prior to the Applicable Issuance Deadline, then the Applicable Warrant Shares subject to such Applicable Issuance Event shall never become exercisable pursuant to this Warrant. For the avoidance of doubt, if none of the Applicable Issuance Events have occurred on or prior to the Third Tranche Issuance Deadline, then this Warrant shall immediately terminate and be of no further force and effect.

(b) Exercise of Warrant. Exercise of the Applicable Warrant Shares, if exercisable in accordance with Section 2(a), may be made by delivery to the Company (or such other office or agency of the Company as it may designate by notice in writing to the registered Holder at the address of the Holder appearing on the books of the Company) of a duly executed

PDF copy submitted by e-mail (or e-mail attachment) of the Notice of Exercise in the form annexed hereto (the "Notice of Exercise") and, within the earlier of (i) 12:00 p.m. (Eastern Time) on the second Trading Day and (ii) 12:00 p.m. (Eastern Time) on the last Trading Day of the applicable Standard Settlement Period following the date said Notice of Exercise is delivered to the Company, payment of the aggregate Exercise Price of the Applicable Warrant Shares thereby purchased pursuant to the applicable Notice of Exercise by wire transfer or cashier's check drawn on a United States bank (including an international branch office of a United States bank) or pursuant to the cashless exercise procedure specified in Section 2(d) below if specified in the applicable Notice of Exercise. No ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise be required. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company until the Holder has purchased all of the Applicable Warrant Shares available hereunder and the Warrant has been terminated or exercised in full, in which case, the Holder shall surrender this Warrant to the Company for cancellation within two (2) Trading Days of the date of termination or the final Notice of Exercise is delivered to the Company. Partial exercises of this Warrant resulting in purchases of a portion of the total number of Applicable Warrant Shares available hereunder shall have the effect of lowering the outstanding number of Applicable Warrant Shares purchasable hereunder in an amount equal to the applicable number of Applicable Warrant Shares purchased. The Holder and the Company shall maintain records showing the number of Applicable Warrant Shares purchased and the date of such purchases. The Company shall deliver any objection to any Notice of Exercise within one (1) Business Day of receipt of such notice. The Holder and any assignee, by acceptance of this Warrant, acknowledge and agree that, by reason of the provisions of this paragraph, following the purchase of a portion of the Applicable Warrant Shares hereunder, the number of Applicable Warrant Shares available for purchase hereunder at any given time may be less than the amount stated on the face hereof; provided that the foregoing shall not limit Company's obligations under Section 2(e)(ii).

(c) Exercise Price. The exercise price per Applicable Warrant Share under this Warrant shall be $3.48, subject to adjustment hereunder (the "Exercise Price").

(d) Cashless Exercise. This Warrant may also be exercised, in whole or in part, by means of a "cashless exercise" in which the Holder shall be entitled to receive a number of Applicable Warrant Shares equal to the quotient obtained by dividing [(A-B) * (X)] by (A), where:

(A) = as applicable: (i) the VWAP on the Trading Day immediately preceding the date of the applicable Notice of Exercise if such Notice of Exercise is (1) delivered, in complete and executed

form, pursuant to Section 2(b) hereof on a day that is not a Trading Day or (2) delivered, in complete and executed form, pursuant to Section 2(b) hereof on a Trading Day prior to the opening of "regular trading hours" (as defined in Rule 600(b)(64) of Regulation NMS promulgated under the federal securities laws) on such Trading Day, (ii) the VWAP as of closing of "regular trading hours" on the date of the applicable Notice of Exercise if such Notice of Exercise is, in complete and executed form, delivered to the Company during "regular trading hours" on a Trading Day or within two (2) hours thereafter (including until two (2) hours after the close of "regular trading hours" on a Trading Day) pursuant to Section 2(b) hereof or (iii) the VWAP on the date of the applicable Notice of Exercise if the date of such Notice of Exercise is a Trading Day and such Notice of Exercise is delivered, in complete and executed form, pursuant to Section 2(b) hereof after the close of "regular trading hours" on such Trading Day;

(B) = the Exercise Price per Applicable Warrant Share, as adjusted hereunder; and

(X) = the number of Applicable Warrant Shares, as applicable, that would be issuable upon exercise of this Warrant in accordance with the terms of this Warrant and pursuant to the applicable Notice of Exercise if such exercise were by means of a cash exercise rather than a cashless exercise.

If the foregoing calculation results in a negative number, then no Applicable Warrant Shares shall be issued upon a "cashless exercise" pursuant to this Section 2(d).

(e) Mechanics of Exercise.

(i) Delivery of Applicable Warrant Shares Upon Exercise. The Company shall cause the Applicable Warrant Shares purchased hereunder to be transmitted by the Transfer Agent to the Holder by crediting the account of the Holder's or its designee's balance account with The Depository Trust Company through its Deposit or Withdrawal at Custodian system ("DWAC") if the Company is then a participant in such system and either (A) there is an effective registration statement permitting the issuance of the Applicable Warrant Shares to or resale of the Applicable Warrant Shares by the Holder or (B) the Applicable Warrant Shares are eligible for resale by the Holder without volume or manner-of-sale limitations pursuant to Rule 144 (assuming cashless exercise of the Warrant), and otherwise by electronic book entry credit or physical delivery of a certificate, registered in the Company's share register in the name of the Holder or its designee, for the number of Applicable Warrant Shares to which the Holder is entitled pursuant to such exercise to the address specified by the Holder in the Notice of Exercise by the date that is the earliest of (1) two (2) Trading Days after the delivery to the Company of the Notice of Exercise, (2) one (1) Trading Day after delivery of the aggregate Exercise Price to the Company and (3) the number of Trading Days comprising the Standard Settlement Period after the delivery to the

Company of the Notice of Exercise (such date, the "Applicable Warrant Share Delivery Date"); provided, under no circumstances is the Company required to cause the Applicable Warrant Shares to be delivered prior to payment of the aggregate Exercise Price (other than in the case of a cashless exercise) with respect to such Applicable Warrant Shares being exercised. Upon delivery of the Notice of Exercise, the Holder shall be deemed for all corporate purposes to have become the holder of record of the Applicable Warrant Shares with respect to which this Warrant has been exercised (including with respect to Applicable Warrant Shares transmitted by crediting the account of the Holder's or its designee's balance account with the Depository Trust Company through its DWAC system), irrespective of the date of delivery of the Applicable Warrant Shares; provided that, payment of the aggregate Exercise Price (other than in the case of a cashless exercise) for such Applicable Warrant Shares is received within the earlier of (i) two (2) Trading Days and (ii) the number of Trading Days comprising the Standard Settlement Period following delivery of the Notice of Exercise.

(ii) Delivery of New Warrants Upon Exercise. If this Warrant shall have been exercised in part, the Company shall, at the request of a Holder and upon surrender of this Warrant certificate, at the time of delivery of the Applicable Warrant Shares, deliver to the Holder a new Warrant evidencing the rights of the Holder to purchase the unpurchased Applicable Warrant Shares that are exercisable at such time by this Warrant, which new Warrant shall in all other respects be identical with this Warrant.

(iii) Rescission Rights. Subject to the Company's receipt of the aggregate Exercise Price for the Applicable Warrant Shares subject to such Notice of Exercise, if the Company fails to cause the Transfer Agent to transmit to the Holder the Applicable Warrant Shares pursuant to Section 2(e)(i) by the Applicable Warrant Share Delivery Date, then the Holder will have the right to rescind such exercise by delivering written notice to the Company at any time prior to the Company delivering such Applicable Warrant Shares.

(iv) No Fractional Shares or Scrip. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Warrant. As to any fraction of a share which the Holder would otherwise be entitled to purchase upon such exercise, the Company shall, at its election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the Exercise Price with respect to the Applicable Warrant Shares being exercised or round up to the next whole share.

(v) Charges, Taxes and Expenses. Issuance of Applicable Warrant Shares shall be made without charge to the Holder for any issue or transfer tax or other incidental expense in respect of the issuance of such Applicable Warrant Shares, all of which taxes and expenses shall be paid by the Company, and such Applicable Warrant Shares shall be issued in the name of the Holder or in such name or names as may be directed by the Holder; provided, however, that in the event that Applicable Warrant Shares are to be issued in a name other than the name of the Holder, this Warrant when surrendered for exercise shall be accompanied by the Assignment Form attached hereto as Exhibit B (the "Assignment Form") duly executed by the Holder and the Company may require, as a condition thereto, the payment of a sum sufficient to reimburse it for any transfer tax incidental thereto.

(vi) Closing of Books. The Company will not close its stockholder books or records in any manner which prevents the timely exercise of this Warrant, pursuant to the terms hereof.

(vii) Resale Registration Rights. In the event that the Company, at any time prior to the Termination Date, proposes to file on behalf of one or more stockholders of the Company a registration statement under the Securities Act pursuant to that certain Second Amended and Restated Investors' Rights Agreement, dated April 16, 2021, by and among the Company and the investors party thereto (as amended from time to time, the "Investor Rights Agreement"), the Company shall provide written notice to the Holder as soon as practicable of such proposed filing, but in no event shall such written notice be given to the Holder later than five (5) days prior to the date that the Company intends to file such registration statement, and the Holder shall have the right to include the Applicable Warrant Shares in such registration statement upon written notice to the Company within two (2) days after the date the Company provides written notice to the Holder; provided, however, that, the rights of the Holder to include Applicable Warrant Shares in such registration statement pursuant to this Section (2)(e)(vii) shall be subordinate to the rights of the investors party to the Investor Rights Agreement, and Holder shall only be permitted to include the Applicable Warrant Shares in such registration statement after all investors party to the Investor Rights Agreement have had the opportunity to include the registration and offering of all shares of Registrable Securities (as defined in the Investor Rights Agreement) that they wish to so include in such registration statement. Notwithstanding anything to the contrary contained herein, the Company shall not be required to file any registration statement pursuant to this Section 2(e)(vii) if at the time of such request (A) the Company is not eligible to file a Form S-3 for such sales, or (B) the Holder can sell all issued Applicable Warrant Shares without restriction pursuant to Rule 144 under the Securities Act; provided, further that the Company's obligations to file a registration statement pursuant to this Section 2(e)(vii) is subject to the receipt by the Company of any information of the Holder reasonably required to be included in the registration statement.

(f) Holder's Exercise Limitations. The Company shall not effect any exercise of this Warrant, and the Holder shall not have the right to exercise any portion of this Warrant, pursuant to Section 2 or otherwise, to the extent that after giving effect to such issuance after exercise as set forth on the applicable Notice of Exercise, the Holder (together with the Holder's Affiliates, and any other Persons acting as a group together with the Holder or any of the Holder's Affiliates), would beneficially own in excess of the Beneficial Ownership Limitation (as defined below). For purposes of the foregoing sentence, the number of shares of Common Stock beneficially owned by the Holder and its Affiliates shall include the number of shares of Common Stock issuable upon exercise of this Warrant with respect to which such determination is being made, but shall exclude the number of shares of Common Stock which would be issuable upon (i) exercise of the remaining, nonexercised portion of this Warrant beneficially owned by the Holder or any of its Affiliates and (ii) exercise or conversion of the unexercised or nonconverted portion of any other securities of the Company (including, without limitation, any other Common Stock Equivalents) subject to a limitation on conversion or exercise analogous to the limitation contained

herein beneficially owned by the Holder or any of its Affiliates. Except as set forth in the preceding sentence, for purposes of this Section 2(f), beneficial ownership shall be calculated in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder, it being acknowledged by the Holder that the Company is not representing to the Holder that such calculation is in compliance with Section 13(d) of the Exchange Act and the Holder is solely responsible for any schedules required to be filed in accordance therewith. To the extent that the limitation contained in this Section 2(f) applies, the determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable shall be in the sole discretion of the Holder, and the submission of a Notice of Exercise shall be deemed to be the Holder's determination of whether this Warrant is exercisable (in relation to other securities owned by the Holder together with any Affiliates) and of which portion of this Warrant is exercisable, in each case subject to the Beneficial Ownership Limitation, and the Company shall have no obligation to verify or confirm the accuracy of such determination and shall have no liability for exercises of the Warrant that are in non-compliance with the Beneficial Ownership Limitation. In addition, a determination as to any group status as contemplated above shall be determined in accordance with Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder. For purposes of this Section 2(f), in determining the number of outstanding shares of Common Stock, a Holder may rely on the number of outstanding shares of Common Stock as reflected in (A) the Company's most recent periodic or annual report filed with the Commission, as the case may be, (B) a more recent public announcement by the Company or (C) a more recent written notice by the Company or the Transfer Agent setting forth the number of shares of Common Stock outstanding. Upon the written or oral request of a Holder, the Company shall within two Trading Days confirm orally and in writing to the Holder the number of shares of Common Stock then outstanding. In any case, the number of outstanding shares of Common Stock shall be determined after giving effect to the conversion or exercise of securities of the Company, including this Warrant, by the Holder or its Affiliates since the date as of which such number of outstanding shares of Common Stock was reported. The "Beneficial Ownership Limitation" shall be 4.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock issuable upon exercise of this Warrant. The Holder, upon not less than 61 days' prior notice to the Company, may increase or decrease the Beneficial Ownership Limitation provisions of this Section 2(f), provided that the Beneficial Ownership Limitation in no event exceeds 19.99% of the number of shares of the Common Stock outstanding immediately after giving effect to the issuance of shares of Common Stock upon exercise of this Warrant held by the Holder and the provisions of this Section 2(f) shall continue to apply. Any such increase or decrease will not be effective until the 61st day after

such notice is delivered to the Company and shall only be effective with respect to such Holder. The provisions of this paragraph shall be construed and implemented in a manner otherwise than in strict conformity with the terms of this Section 2(f) to correct this paragraph (or any portion hereof) which may be defective or inconsistent with the intended Beneficial Ownership Limitation herein contained or to make changes or supplements necessary or desirable to properly give effect to such limitation. The limitations contained in this paragraph shall apply to a successor holder of this Warrant.

Section 3.Certain Adjustments.

(a) Stock Dividends and Splits. If the Company, at any time while this Warrant is outstanding: (i) pays a stock dividend or otherwise makes a distribution or distributions on shares of its Common Stock or any other equity or equity equivalent securities payable in shares of Common Stock (which, for avoidance of doubt, shall not include any shares of Common Stock issued by the Company upon exercise of this Warrant), (ii) subdivides (including by way of stock split) outstanding shares of Common Stock into a larger number of shares or (iii) combines (including by way of reverse stock split) outstanding shares of Common Stock into a smaller number of shares, then in each case the Exercise Price shall be multiplied by a fraction of which the numerator shall be the number of shares of Common Stock (excluding treasury shares, if any) outstanding immediately before such event and of which the denominator shall be the number of shares of Common Stock outstanding immediately after such event, and the number of shares issuable upon exercise of this Warrant shall be proportionately adjusted such that the aggregate Exercise Price of this Warrant shall remain unchanged, subject to the limitation on fractional shares in Section 2(e)(iv). Any adjustment made pursuant to this Section 3(a) shall become effective immediately after the record date for the determination of stockholders entitled to receive such dividend or distribution and shall become effective immediately after the effective date in the case of a subdivision, combination or re-classification.

(b) Reclassifications. If at any time prior to the Termination Date while this Warrant remains outstanding and unexpired in whole or in part, the Common Stock issuable upon exercise of this Warrant is changed into the same or a different number of shares of any class or classes of stock, this Warrant will thereafter represent the right to acquire such number and kind of securities as would have been issuable as a result of exercise of this Warrant and the Exercise Price therefor shall be appropriately adjusted.

(c) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest 1/100th of a share, as the case may be. For purposes of this Section 3, the number of shares of Common Stock deemed to be issued and outstanding as of a given date shall be the sum of

the number of shares of Common Stock (excluding treasury shares, if any) issued and outstanding.

(d) Notice to Holder.

(i) Adjustment to Exercise Price. Whenever the Exercise Price is adjusted pursuant to any provision of this Section 3, the Company shall promptly deliver to the Holder by email a notice setting forth the Exercise Price after such adjustment and any resulting adjustment to the number of Applicable Warrant Shares and setting forth a brief statement of the facts requiring such adjustment.

(ii) Notice to Allow Exercise by Holder. If during the term in which this Warrant may be exercised by the Holder (A) the Company shall declare a dividend or any other distribution in whatever form (except a dividend or distribution subject to Section 3(a)) on the Common Stock, (B) the Company shall declare a redemption of the Common Stock, (C) the Company shall authorize the granting to all holders of the Common Stock rights or warrants to subscribe for or purchase any shares of capital stock of any class or of any rights, (D) the Company proposes to effect a Fundamental Transaction, or (E) the Company shall authorize the voluntary or involuntary dissolution, liquidation or winding up of the affairs of the Company, then, in each case, the Company shall cause to be delivered by email to the Holder at its last email address as it shall appear upon the Warrant Register of the Company, at least ten (10) calendar days prior to the applicable record or effective date hereinafter specified or the proposed date of closing in the case of a Fundamental Transaction setting forth a brief description of such proposed transaction and (x) the date on which a record is to be taken for the purpose of such dividend, distribution, redemption, rights or warrants, or if a record is not to be taken, the date as of which the holders of the Common Stock of record to be entitled to such dividend, distributions, redemption, rights or warrants are to be determined (the "Record Date") or (y) the date on which such Fundamental Transaction is expected to become effective or close, and the date as of which it is expected that holders of the Common Stock of record shall be entitled to exchange their shares of Common Stock for securities, cash or other property deliverable upon such Fundamental Transaction. To the extent that any notice provided in this Warrant would constitute, or contain, material, non-public information regarding the Company or any of its Subsidiaries, then prior to delivering such notice, the Company shall promptly request the Holder's agreement to receive material non-public information and to hold such information in confidence (without disclosing the nature of such information). If the Holder does not so agree, then the Company shall be excused from delivering the notice; provided that the Company shall promptly deliver such notice after such time, if any, that delivery would not provide the Holder with material non-public information regarding the Company or any of its Subsidiaries. The Holder shall not be entitled to any such dividend, distribution, redemption, rights or warrants if the Holder does not exercise this Warrant on or prior to the Record Date. This Warrant shall terminate in all respects and no longer be exercisable upon the closing of a Fundamental Transaction; provided that, unless the Holder otherwise provides written notice to the Company, immediately prior to the closing of such Fundamental Transaction, this Warrant shall be deemed to be automatically exercised with respect to all Applicable Warrant Shares then-exercisable in accordance with Section 2(a).

Section 4.Transfer of Warrant.

(a) Transferability. Subject to compliance with applicable securities laws, this Warrant and all rights hereunder are transferable, in whole or in part, upon surrender of this Warrant at the principal office of the Company, together with an Assignment Form duly executed by the Holder or its agent or attorney and funds sufficient to pay any transfer taxes payable upon the making of such transfer. Prior to any such transfer, the transferee shall deliver a written statement to the Company that such transferee is an "accredited investor" as defined in Rule 501(a) promulgated under the Securities Act, and in the case of a transaction exempt from registration under the Securities Act, shall provide documentation reasonably satisfactory to the Company that such transaction does not require registration under the Securities Act. Upon such surrender and, if required, such payment, the Company shall execute and deliver a new Warrant or Warrants in the name of the assignee or assignees, as applicable, in the denomination or denominations specified in such instrument of assignment and bearing appropriate legends, and shall issue to the assignor a new Warrant evidencing the portion of this Warrant not so assigned, and this Warrant shall promptly be cancelled. Notwithstanding anything herein to the contrary, the Holder shall not be required to physically surrender this Warrant to the Company unless the Holder has assigned this Warrant in full, in which case, the Holder shall surrender this Warrant to the Company within three (3) Trading Days of the date the Holder delivers an Assignment Form to the Company assigning this Warrant in full. The Warrant, if properly assigned in accordance herewith, may be exercised by a new holder for the purchase of the Applicable Warrant Shares that are exercisable without having a new Warrant issued.

(b) New Warrants. This Warrant may be divided or combined with other Warrants upon presentation hereof at the aforesaid office of the Company, together with a written notice specifying the names and denominations in which new Warrants are to be issued, signed by the Holder or its agent or attorney. Subject to compliance with Section 4(a), as to any transfer which may be involved in such division or combination, the Company shall execute and deliver a new Warrant or Warrants in exchange for the Warrant or Warrants to be divided or combined in accordance with such notice. All Warrants issued on transfers or exchanges shall be identical to this Warrant except as to the number of Applicable Warrant Shares issuable pursuant thereto.

(c) Warrant Register. The Company shall register this Warrant, upon records to be maintained by the Company for that purpose (the "Warrant Register"), in the name of the record Holder hereof from time to time. The Company may deem and treat the registered Holder of this Warrant as the absolute owner hereof for the purpose of any exercise hereof or any distribution to the Holder, and for all other purposes, absent actual written notice to the contrary.

(d) Procedures Regarding Loss, Theft, Destruction or Mutilation of Warrant. If (a) this Warrant is mutilated and is surrendered to the Company for replacement or (b) both (i) there shall be delivered to the Company (A) a claim by Holder as to the destruction, loss or wrongful taking of this Warrant and a request thereby for a new replacement Warrant, and (B) such indemnity bond as may be required by the Company to save it and any agent of it as harmless and (ii) such other reasonable requirements as may be imposed by the Company as permitted by Section 8-405 of the Uniform Commercial Code have been satisfied, then, in the absence of notice to the Company that such Warrant has been acquired by a "protected purchaser" within the meaning of Section 8-405 of the Uniform Commercial Code, the Company shall execute and deliver to the registered Holder of the lost, wrongfully taken, destroyed or mutilated Warrant, in exchange therefor or in lieu thereof, a new Warrant of the same tenor and for a like aggregate number of Warrants. Upon the issuance of any new Warrant under this Section 4(d), the Company may require the payment of a sum sufficient to cover any tax or other governmental charge that may be imposed in relation thereto and other expenses (including the fees and expenses of counsel to the Company) in connection therewith.

(e) Representations and Warranties by the Holder. The Holder represents and warrants to the Company as follows:

(i) Purchase for Own Account. This Warrant and the Applicable Warrant Shares acquired upon exercise of this Warrant by the Holder will be acquired for investment for the Holder's account, not as a nominee or agent, and not with a view to the public resale or distribution within the meaning of the Securities Act and the Holder has no present intention of selling or engaging in any public distribution of the same except pursuant to a registration or exemption. The Holder also represents that the Holder has not been formed for the specific purpose of acquiring this Warrant or the Applicable Warrant Shares.

(ii) Disclosure of Information. The Holder has received or has had full access to all the information it considers necessary or appropriate to make an informed investment decision with respect to the acquisition of this Warrant and the Applicable Warrant Shares. The Holder further has had an opportunity to ask questions and receive answers from the Company regarding the terms and conditions of the offering of this Warrant and the Applicable Warrant Shares and to obtain additional information (to the extent the Company possessed such information or could acquire it without unreasonable effort or expense) necessary to verify any information furnished to the Holder or to which the Holder has access.

(iii) Investment Experience. The Holder understands that the acquisition of this Warrant and its underlying securities involves substantial risk. The Holder has experience as an investor in securities of companies similarly situated to the Company and acknowledges that the Holder can bear the economic risk of the Holder's investment in this Warrant and the Applicable Warrant Shares and has such knowledge and experience in financial or business matters that the Holder is capable of evaluating the merits and risks of its investment in this Warrant and the Applicable Warrant Shares and/or has a preexisting personal or business relationship with the

Company and certain of its officers, directors or controlling persons of a nature and duration that enables the Holder to be aware of the character, business acumen and financial circumstances of such persons.

(iv) Accredited Investor Status; Principal Office. The Holder is an "accredited investor" within the meaning of Regulation D promulgated under the Securities Act. The Holder's principal place of business is as set forth on the signature page hereto.

(v) The Securities Act. The Holder understands that this Warrant and the Applicable Warrant Shares issuable upon exercise hereof have not been registered under the Securities Act in reliance upon a specific exemption therefrom, which exemption depends upon, among other things, the bona fide nature of Holder's investment intent as expressed herein. The Holder understands that this Warrant and the Applicable Warrant Shares issued upon any exercise hereof must be held indefinitely unless subsequently registered under the Securities Act and qualified under applicable state securities laws, or unless exemption from such registration and qualification are otherwise available.

Section 5.Miscellaneous.

(a) No Rights as Stockholder Until Exercise; No Settlement in Cash. This Warrant does not entitle the Holder to any voting rights, dividends or other rights as a stockholder of the Company prior to the exercise hereof as set forth in Section 2(e)(i), except as expressly set forth in Section 3. Without limiting the rights of a Holder to receive Applicable Warrant Shares on a "cashless exercise" pursuant to Section 2(d) or cash in lieu of fractional shares pursuant to Section 2(e)(iv), in no event will the Company be required to pay cash in lieu of issuance of Applicable Warrant Shares upon exercise.

(b) Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then, such action may be taken or such right may be exercised on the next succeeding Business Day.

(c) Authorized Shares.

The Company covenants that, during the period the Warrant is outstanding, it will reserve from its authorized and unissued Common Stock a sufficient number of shares free from preemptive rights to provide for the issuance of the Applicable Warrant Shares upon the exercise of any purchase rights under this Warrant and to take all steps necessary to increase the authorized number of shares of its Common Stock if at any time the authorized number of shares of Common Stock remaining unissued is insufficient to permit the exercise of this Warrant. The Company further covenants that its issuance of this Warrant shall constitute full authority to its officers who are charged with the duty of issuing the necessary Applicable Warrant Shares upon the exercise of the purchase rights under this Warrant. The Company will take all such reasonable action as may be necessary to assure that such Applicable Warrant Shares may be issued as provided herein without violation of any applicable law or regulation, or of any requirements of the Trading Market

upon which the Common Stock may be listed. The Company covenants that all Applicable Warrant Shares which may be issued upon the exercise of the purchase rights represented by this Warrant will, upon exercise of the purchase rights represented by this Warrant and payment for such Applicable Warrant Shares in accordance herewith, be duly authorized, validly issued, fully paid and nonassessable and free from all taxes, liens and charges created by the Company in respect of the issue thereof (other than taxes in respect of any transfer occurring contemporaneously with such issue).

Except and to the extent as waived or consented to by the Holder, the Company shall not by any action, including, without limitation, amending its certificate of incorporation or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Warrant, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate to protect the rights of Holder as set forth in this Warrant against impairment. Without limiting the generality of the foregoing, the Company will (i) not increase the par value of any Applicable Warrant Shares above the amount payable therefor upon such exercise immediately prior to such increase in par value, (ii) take all such action as may be necessary or appropriate in order that the Company may validly and legally issue fully paid and nonassessable Applicable Warrant Shares upon the exercise of this Warrant and (iii) use commercially reasonable efforts to obtain all such authorizations, exemptions or consents from any public regulatory body having jurisdiction thereof, as may be necessary to enable the Company to perform its obligations under this Warrant.

Before taking any action which would result in an adjustment in the number of Applicable Warrant Shares for which this Warrant is exercisable or in the Exercise Price, the Company shall obtain all such authorizations or exemptions thereof, or consents thereto, as may be necessary from any public regulatory body or bodies having jurisdiction thereof.

(d) Jurisdiction. All questions concerning the construction, validity, enforcement and interpretation of this Warrant shall be governed by and construed and enforced in accordance with the internal laws of the State of New York, without regard to the principles of conflict of laws thereof.

(e) Restrictions. The Holder acknowledges that the Applicable Warrant Shares acquired upon the exercise of this Warrant, if not registered, and the Holder does not utilize cashless exercise, may have restrictions upon resale imposed by state and federal securities laws.

(f) Nonwaiver and Expenses. No course of dealing or any delay or failure to exercise any right hereunder on the part of Holder shall operate as a waiver of such right or otherwise prejudice the Holder’s rights, powers or remedies.

(g) Notices. Any and all notices or other communications or deliveries hereunder (including, without limitation, any Notice of Exercise) shall be in writing and shall be deemed given and as follows:

If to the Company, to it at:

1601 Trapelo Rd., Suite 178
Waltham, MA 02451
Attention: David Hering, Chief Executive Officer
Email Address: dhering@invivyd.com

with a copy (which shall not constitute notice) to:

1601 Trapelo Rd., Suite 178
Waltham, MA 02451
Attention: Jill Andersen, Chief Legal Officer
Email Address: jandersen@invivyd.com

or

If to the Holder, to it at:

Population Health Partners, L.P.
1200 Morris Turnpike, Suite 3005
Short Hills, NJ 07078
Attention: Chris Cox
E-mail Address: chris.cox@populationhp.com

with copies (which shall not constitute notice) to:

Paul, Weiss, Rifkind, Wharton & Garrison LLP
1285 Avenue of the Americas
New York, NY 10019-6064
Attention: Neil Goldman
Email Address: ngoldman@paulweiss.com

Such notices shall be effective on the earliest of (i) the time of transmission, if such notice or communication is delivered via e-mail at the e-mail address specified above prior to 5:30 P.M., New York City time, on a Trading Day (provided, with respect to delivery by e-mail, that such sent e-mail is kept on file (whether electronically or otherwise) by the sending party and the sending party does not receive an automatically generated message from the recipient's e-mail server that such e-mail could not be delivered to such recipient), (ii) the next Trading Day after the date of transmission, if such notice or communication is delivered via e-mail at the e-mail address specified above on a day that is not a Trading Day or later than 5:30 P.M., New York City time, on any Trading Day (provided, with respect to delivery by e-mail, that such sent e-mail is kept on file (whether electronically or otherwise) by the sending party and the sending party does not receive an automatically generated message from the recipient's e-mail server that such e-mail could not be delivered to such recipient), (iii) the Trading Day following the date of mailing, if sent by nationally recognized overnight courier service specifying next Business Day delivery, or (iv) upon actual receipt by the Person to whom such notice is required to be given, if by hand delivery.

(h) Limitation of Liability. No provision hereof, in the absence of any affirmative action by the Holder to exercise this Warrant to purchase Applicable Warrant Shares, and no enumeration herein of the rights or privileges of the Holder, shall give rise to any liability of the Holder for the purchase price of any Common Stock or as a stockholder of the Company, whether such liability is asserted by the Company or by creditors of the Company.

(i) Remedies. The Holder, in addition to being entitled to exercise all rights granted by law, including recovery of damages, will be entitled to specific performance of its rights under this Warrant. The Company agrees that monetary damages would not be adequate compensation for any loss incurred by reason of a breach by it of the provisions of this Warrant and hereby agrees to waive and not to assert the defense in any action for specific performance that a remedy at law would be adequate.

(j) Successors and Assigns. Subject to applicable securities laws, this Warrant and the rights and obligations evidenced hereby shall inure to the benefit of and be binding upon the successors of the Company and the successors and permitted assigns of Holder. The provisions of this Warrant are intended to be for the benefit of any Holder from time to time of this Warrant and shall be enforceable by the Holder or holder of Applicable Warrant Shares. Nothing in this Warrant, express or implied, is intended to confer upon any person other than the Company, the Holder or holder of the Warrants, any rights or remedies upon or by reason of this Warrant or any part thereof. The Holder may assign this Warrant in accordance with the provisions set forth in Section 4.

(k) Amendment. This Warrant may be modified or amended or the provisions hereof waived with the written consent of the Company and the Holder.

(l) Severability. Wherever possible, each provision of this Warrant shall be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Warrant shall be prohibited by or invalid under applicable law, such provision shall be ineffective to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Warrant.

(m) Headings. The headings used in this Warrant are for the convenience of reference only and shall not, for any purpose, be deemed a part of this Warrant.

(n) Counterparts. This Warrant may be executed in two or more counterparts, each of which will be deemed to be an original, but all of which together constitute one and the same instrument.

(Signature Page Follows)

IN WITNESS WHEREOF, the Company has caused this Warrant to be executed by its officer thereunto duly authorized as of the date first above indicated.

INVIVYD, INC.

By: /s/ David Hering, M.B.A.
Name: David Hering, M.B.A.
Title: Chief Executive Officer

[COMPANY SIGNATURE PAGE TO WARRANT]

Acknowledged, accepted and agreed,

POPULATION HEALTH PARTNERS, L.P.

By: /s/ Chris Cox
Name: Chris Cox
Title: Managing Member

EXHIBIT A

NOTICE OF EXERCISE

TO: INVIVYD, INC.

(1) The undersigned hereby elects to purchase _____ [First Tranche Shares [and/or] Second Tranche Shares [and/or] Third Tranche Shares] of the Company pursuant to the terms of the attached Warrant, and tenders herewith payment of the Exercise Price with respect to the Applicable Warrant Shares in full, together with all applicable transfer taxes, if any.

(2) Payment shall take the form of (check applicable box):

☐ by wire transfer or cashier's check drawn on a United States bank per Section 2(b); or

☐ cashless exercise procedure set forth in Section 2(d).

(3) Please issue said Applicable Warrant Shares in the name of the undersigned or in such other name as is specified below:

The Applicable Warrant Shares shall be delivered:

(i) to the following DWAC Account Number:

or

(ii) in electronic book-entry credit or certificated form in the name and at the address of the following Holder:

(4) Accredited Investor. The undersigned is an "accredited investor" as defined in Regulation D promulgated under the Securities Act of 1933, as amended.

[SIGNATURE OF HOLDER]

Name of Investing Entity:

Signature of Authorized Signatory of Investing Entity:

Name of Authorized Signatory:
Title of Authorized Signatory:
Date:

EXHIBIT B

ASSIGNMENT FORM

(To assign the foregoing Warrant, execute this form and supply required information.

Do not use this form to exercise the Warrant.)

FOR VALUE RECEIVED, [_____] all of [_____] First Tranche Shares [and/or] [_____] Second Tranche Shares [and/or] [_____] Third Tranche Shares of the foregoing Warrant and all rights evidenced thereby are hereby assigned to

Name: _____
(Please Print)

Address: _____
(Please Print)

Phone Number: _____

Email Address: _____

Dated: _____ __, _____

Holder's Signature: _____

Holder's Address: _____

NOTE: The signature to this Assignment Form must correspond with the name as it appears on the face of the Warrant, without alteration or enlargement or any change whatsoever, and must be guaranteed by a bank or trust company. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Warrant.

Exhibit 10.4

INVIVYD, INC.

INDEMNIFICATION AGREEMENT

This Indemnification Agreement (this "***Agreement***") is dated as of _____, 20__, and is between Invivyd, Inc., a Delaware corporation (the "***Company***"), and _____ ("***Indemnitee***").

RECITALS

A. Indemnitee's service to the Company substantially benefits the Company.

B. Individuals are reluctant to serve as directors or officers of corporations or in certain other capacities unless they are provided with adequate protection through insurance or indemnification against the risks of claims and actions against them arising out of such service.

C. Indemnitee does not regard the protection currently provided by applicable law, the Company's governing documents and any insurance as adequate under the present circumstances, and Indemnitee may not be willing to serve as a director or officer without additional protection.

D. In order to induce Indemnitee to continue to provide services to the Company, it is reasonable, prudent and necessary for the Company to contractually obligate itself to indemnify, and to advance expenses on behalf of, Indemnitee as permitted by applicable law.

E. This Agreement is a supplement to and in furtherance of the indemnification provided in the Company's certificate of incorporation and bylaws, and any resolutions adopted pursuant thereto, and this Agreement shall not be deemed a substitute therefor, nor shall this Agreement be deemed to limit, diminish or abrogate any rights of Indemnitee thereunder.

The parties therefore agree as follows:

1. Definitions.

(a) A "***Change in Control***" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

(i) *Acquisition of Stock by Third Party.* Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities;

(ii) *Change in Board Composition.* During any period of two consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Company's board of directors, and any new directors (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 1(a)(i), 1(a)(iii) or 1(a)(iv)) whose election by the board of directors or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Company's board of directors;

(iii) *Corporate Transactions.* The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting

securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 50% of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity;

(iv) *Liquidation.* The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and

(v) *Other Events.* Any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or in response to any similar item on any similar schedule or form) promulgated under the Securities Exchange Act of 1934, as amended, whether or not the Company is then subject to such reporting requirement.

For purposes of this Section 1(a), the following terms shall have the following meanings:

(1) "***Person***" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended; *provided, however,* that "***Person***" shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(2) "***Beneficial Owner***" shall have the meaning given to such term in Rule 13d-3 under the Securities Exchange Act of 1934, as amended; *provided, however,* that "***Beneficial Owner***" shall exclude any Person otherwise becoming a Beneficial Owner by reason of (i) the stockholders of the Company approving a merger of the Company with another entity or (ii) the Company's board of directors approving a sale of securities by the Company to such Person.

(b) "***Corporate Status***" describes the status of a person who is or was a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of the Company or any other Enterprise.

(c) "***DGCL***" means the General Corporation Law of the State of Delaware.

(d) "***Disinterested Director***" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(e) "***Enterprise***" means the Company and any other corporation, partnership, limited liability company, joint venture, trust, employee benefit plan or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary.

(f) "***Expenses***" include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees and costs of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedes bond or other appeal bond or their equivalent, and (ii) for purposes of Section 12(d), Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this

Agreement or under any directors' and officers' liability insurance policies maintained by the Company. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(g) "***Independent Counsel***" means a law firm, or a partner or member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent (i) the Company or Indemnitee in any matter material to either such party (other than as Independent Counsel with respect to matters concerning Indemnitee under this Agreement, or other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "***Independent Counsel***" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement.

(h) "***Proceeding***" means any threatened, pending or completed action, suit, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative or investigative nature, including any appeal therefrom and including without limitation any such Proceeding pending as of the date of this Agreement, in which Indemnitee was, is or will be involved as a party, a potential party, a nonparty witness or otherwise by reason of (i) the fact that Indemnitee is or was a director or officer of the Company, (ii) any action taken by Indemnitee or any action or inaction on Indemnitee's part while acting as a director or officer of the Company, or (iii) the fact that he or she is or was serving at the request of the Company as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of the Company or any other Enterprise, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification or advancement of expenses can be provided under this Agreement.

(i) Reference to "***other enterprises***" shall include employee benefit plans; references to "***fines***" shall include any excise taxes assessed on a person with respect to any employee benefit plan; references to "***serving at the request of the Company***" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he or she reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in a manner "***not opposed to the best interests of the Company***" as referred to in this Agreement.

2. Indemnity in Third-Party Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 2 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 2, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred by Indemnitee or on his or her behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Company and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was unlawful.

3. Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent

permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 3 in respect of any claim, issue or matter as to which Indemnitee shall have been adjudged by a court of competent jurisdiction to be liable to the Company, unless and only to the extent that the Delaware Court of Chancery or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification for such expenses as the Delaware Court of Chancery or such other court shall deem proper.

4. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. To the extent that Indemnitee is a party to or a participant in and is successful (on the merits or otherwise) in defense of any Proceeding or any claim, issue or matter therein, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith. To the extent permitted by applicable law, if Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, in defense of one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with (a) each successfully resolved claim, issue or matter and (b) any claim, issue or matter related to any such successfully resolved claim, issue or matter. For purposes of this section, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

5. Indemnification for Expenses of a Witness. To the extent that Indemnitee is, by reason of his or her Corporate Status, a witness in any Proceeding to which Indemnitee is not a party, Indemnitee shall be indemnified to the extent permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection therewith.

6. Additional Indemnification.

(a) Notwithstanding any limitation in Sections 2, 3 or 4, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) against all Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred by Indemnitee or on his or her behalf in connection with the Proceeding or any claim, issue or matter therein.

(b) For purposes of Section 6(a), the meaning of the phrase "***to the fullest extent permitted by applicable law***" shall include, but not be limited to:

(i) the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL; and

(ii) the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

7. Exclusions. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnity in connection with any Proceeding (or any part of any Proceeding):

(a) for which payment has actually been made to or on behalf of Indemnitee under any statute, insurance policy, indemnity provision, vote or otherwise, except with respect to any excess beyond the amount paid;

(b) for an accounting or disgorgement of profits pursuant to Section 16(b) of the Securities Exchange Act of 1934, as amended, or similar provisions of federal, state or local statutory law or common law, if Indemnitee is held liable therefor (including pursuant to any settlement arrangements);

(c) for any reimbursement of the Company by Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by Indemnitee from the sale of securities of the Company, as required in each case under the Securities Exchange Act of 1934, as amended (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "***Sarbanes-Oxley Act***"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act), if Indemnitee is held liable therefor (including pursuant to any settlement arrangements);

(d) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees, agents or other indemnitees, unless (i) the Company's board of directors authorized the Proceeding (or the relevant part of the Proceeding) prior to its initiation, (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law, (iii) otherwise authorized in Section 12(d) or (iv) otherwise required by applicable law; or

(e) if prohibited by applicable law.

8. Advances of Expenses. The Company shall advance the Expenses incurred by Indemnitee in connection with any Proceeding, and such advancement shall be made as soon as reasonably practicable, but in any event no later than 60 days, after the receipt by the Company of a written statement or statements requesting such advances from time to time (which shall include invoices received by Indemnitee in connection with such Expenses but, in the case of invoices in connection with legal services, any references to legal work performed or to expenditure made that would cause Indemnitee to waive any privilege accorded by applicable law shall not be included with the invoice). Advances shall be unsecured and interest free and made without regard to Indemnitee's ability to repay such advances. Indemnitee hereby undertakes to repay any advance to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. This Section 8 shall not apply to the extent advancement is prohibited by law and shall not apply to any Proceeding for which indemnity is not permitted under this Agreement, but shall apply to any Proceeding referenced in Section 7(b) or 7(c) prior to a determination that Indemnitee is not entitled to be indemnified by the Company.

9. Procedures for Notification and Defense of Claim.

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses as soon as reasonably practicable following the receipt by Indemnitee of notice thereof. The written notification to the Company shall include, in reasonable detail, a description of the nature of the Proceeding and the facts underlying the Proceeding. The failure by Indemnitee to notify the Company will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights, except to the extent that such failure or delay materially prejudices the Company.

(b) If, at the time of the receipt of a notice of a Proceeding pursuant to the terms hereof, the Company has directors' and officers' liability insurance in effect, the Company shall give prompt notice of the commencement of the Proceeding to the insurers in accordance with the procedures set forth in the applicable policies. The Company shall thereafter take all commercially-reasonable action to cause such insurers to pay, on behalf of Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

(c) In the event the Company may be obligated to make any indemnity in connection with a Proceeding, the Company shall be entitled to assume the defense of such Proceeding with counsel approved by Indemnitee, which approval shall not be unreasonably withheld, upon the delivery to Indemnitee of written notice of its election to do so. After delivery of such notice, approval of such counsel by Indemnitee and the retention of such counsel by the Company, the Company will not be liable to Indemnitee for any fees or expenses of counsel subsequently incurred by Indemnitee with respect to the same Proceeding. Notwithstanding the Company's assumption of the defense of any such Proceeding, the Company shall be obligated to pay the fees and expenses of Indemnitee's counsel to the extent (i) the employment of counsel by Indemnitee is authorized by the Company, (ii) counsel for the Company or Indemnitee shall have reasonably concluded that there is a conflict of interest between the Company and Indemnitee in the conduct of any such defense such that Indemnitee needs to be separately represented, (iii) the fees and expenses are non-duplicative and reasonably incurred in connection with Indemnitee's role in the Proceeding despite the Company's assumption of the defense, (iv) the Company is not financially or legally able to perform its indemnification obligations or (v) the Company shall not have retained, or shall not continue to retain, such counsel to defend such Proceeding. The Company shall have the right to conduct such defense as it sees fit in its sole discretion. Regardless of any provision in this Agreement, Indemnitee shall have the right to employ counsel in any Proceeding at Indemnitee's personal expense. The Company shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Company.

(d) Indemnitee shall give the Company such information and cooperation in connection with the Proceeding as may be reasonably appropriate.

(e) The Company shall not be liable to indemnify Indemnitee for any settlement of any Proceeding (or any part thereof) without the Company's prior written consent, which shall not be unreasonably withheld.

(f) The Company shall not settle any Proceeding (or any part thereof) without Indemnitee's prior written consent, which shall not be unreasonably withheld.

10. Procedures upon Application for Indemnification.

(a) To obtain indemnification, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and as is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of the Proceeding. The Company shall, as soon as reasonably practicable after receipt of such a request for indemnification, advise the board of directors that Indemnitee has requested indemnification. Any delay in providing the request will not relieve the Company from its obligations under this Agreement, except to the extent such failure is prejudicial.

(b) Upon written request by Indemnitee for indemnification pursuant to Section 10(a), a determination, if required by applicable law, with respect to Indemnitee's entitlement thereto shall be made in the specific case (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Company's board of directors, a copy of which shall be delivered to Indemnitee or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors,

even though less than a quorum of the Company's board of directors, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Company's board of directors, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Company's board of directors, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Company's board of directors, by the stockholders of the Company. If it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten days after such determination. Indemnitee shall cooperate with the person, persons or entity making the determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information that is not privileged or otherwise protected from disclosure and that is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or expenses (including attorneys' fees and disbursements) reasonably incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company, to the extent permitted by applicable law.

(c) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 10(b), the Independent Counsel shall be selected as provided in this Section 10(c). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Company's board of directors, and the Company shall give written notice to Indemnitee advising him or her of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Company's board of directors, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; *provided*, *however*, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 1 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or a court has determined that such objection is without merit. If, within 20 days after the later of (i) submission by Indemnitee of a written request for indemnification pursuant to Section 10(a) hereof and (ii) the final disposition of the Proceeding, the parties have not agreed upon an Independent Counsel, either the Company or Indemnitee may petition a court of competent jurisdiction for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and for the appointment as Independent Counsel of a person selected by the court or by such other person as the court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 10(b) hereof. Upon the due commencement of any judicial proceeding pursuant to Section 12(a) of this Agreement, the Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(d) The Company agrees to pay the reasonable fees and expenses of any Independent Counsel and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

11. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person, persons or entity making such determination shall, to the fullest extent not prohibited by law,

presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 10(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by such person, persons or entity of any determination contrary to that presumption.

(b) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of *nolo contendere* or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his or her conduct was unlawful.

(c) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith to the extent Indemnitee relied in good faith on (i) the records or books of account of the Enterprise, including financial statements, (ii) information supplied to Indemnitee by the officers of the Enterprise in the course of their duties, (iii) the advice of legal counsel for the Enterprise or its board of directors or counsel selected by any committee of the board of directors or (iv) information or records given or reports made to the Enterprise by an independent certified public accountant, an appraiser, investment banker or other expert selected with reasonable care by the Enterprise or its board of directors or any committee of the board of directors. The provisions of this Section 11(c) shall not be deemed to be exclusive or to limit in any way the other circumstances in which Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(d) Neither the knowledge, actions nor failure to act of any other director, officer, agent or employee of the Enterprise shall be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

12. Remedies of Indemnitee.

(a) Subject to Section 12(e), in the event that (i) a determination is made pursuant to Section 10 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 8 or 12(d) of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 10 of this Agreement within 90 days after the later of the receipt by the Company of the request for indemnification or the final disposition of the Proceeding, (iv) payment of indemnification pursuant to this Agreement is not made (A) within ten days after a determination has been made that Indemnitee is entitled to indemnification or (B) with respect to indemnification pursuant to Sections 4, 5 and 12(d) of this Agreement, within 30 days after receipt by the Company of a written request therefor, or (v) the Company or any other person or entity takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or proceeding designed to deny, or to recover from, Indemnitee the benefits provided or intended to be provided to Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of competent jurisdiction of his or her entitlement to such indemnification or advancement of Expenses. The Company shall not oppose Indemnitee’s right to seek any such adjudication in accordance with this Agreement.

(b) Neither (i) the failure of the Company, its board of directors, any committee or subgroup of the board of directors, Independent Counsel or stockholders to have made a determination that indemnification of Indemnitee is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor (ii) an actual determination by the Company, its board of directors, any committee or subgroup of the board of directors, Independent Counsel or stockholders that Indemnitee

has not met the applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has or has not met the applicable standard of conduct. In the event that a determination shall have been made pursuant to Section 10 of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding commenced pursuant to this Section 12 shall be conducted in all respects as a *de novo* trial, on the merits, and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding commenced pursuant to this Section 12, the Company shall, to the fullest extent not prohibited by law, have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) To the fullest extent not prohibited by law, the Company shall be precluded from asserting in any judicial proceeding commenced pursuant to this Section 12 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court that the Company is bound by all the provisions of this Agreement. If a determination shall have been made pursuant to Section 10 of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding commenced pursuant to this Section 12, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statements not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) To the extent not prohibited by law, the Company shall indemnify Indemnitee against all Expenses that are incurred by Indemnitee in connection with any action for indemnification or advancement of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company to the extent Indemnitee is successful in such action, and, if requested by Indemnitee, shall (as soon as reasonably practicable, but in any event no later than 60 days, after receipt by the Company of a written request therefor) advance such Expenses to Indemnitee, subject to the provisions of Section 8.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement to indemnification shall be required to be made prior to the final disposition of the Proceeding.

13. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amounts incurred by Indemnitee, whether for Expenses, judgments, fines or amounts paid or to be paid in settlement, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the events and transactions giving rise to such Proceeding; and (ii) the relative fault of Indemnitee and the Company (and its other directors, officers, employees and agents) in connection with such events and transactions.

14. Non-exclusivity. The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Company's certificate of incorporation or bylaws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Company's certificate of incorporation and bylaws and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change, subject to the restrictions expressly set forth herein or therein. Except as expressly set forth herein, no right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in

addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. Except as expressly set forth herein, the assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any other right or remedy.

15. Primary Responsibility. The Company acknowledges that to the extent Indemnitee is serving as a director on the Company's board of directors at the request or direction of a venture capital fund or other entity and/or certain of its affiliates (collectively, the "Secondary Indemnitors"), Indemnitee may have certain rights to indemnification and advancement of expenses provided by such Secondary Indemnitors. The Company agrees that, as between the Company and the Secondary Indemnitors, the Company is primarily responsible for amounts required to be indemnified or advanced under the Company's certificate of incorporation or bylaws or this Agreement and any obligation of the Secondary Indemnitors to provide indemnification or advancement for the same amounts is secondary to those Company obligations. To the extent not in contravention of any insurance policy or policies providing liability or other insurance for the Company or any director, trustee, general partner, managing member, officer, employee, agent or fiduciary of the Company or any other Enterprise, the Company waives any right of contribution or subrogation against the Secondary Indemnitors with respect to the liabilities for which the Company is primarily responsible under this Section 15. In the event of any payment by the Secondary Indemnitors of amounts otherwise required to be indemnified or advanced by the Company under the Company's certificate of incorporation or bylaws or this Agreement, the Secondary Indemnitors shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee for indemnification or advancement of expenses under the Company's certificate of incorporation or bylaws or this Agreement or, to the extent such subrogation is unavailable and contribution is found to be the applicable remedy, shall have a right of contribution with respect to the amounts paid. The Secondary Indemnitors are express third-party beneficiaries of the terms of this Section 15.

16. No Duplication of Payments. The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable hereunder (or for which advancement is provided hereunder) if and to the extent that Indemnitee has otherwise actually received payment for such amounts under any insurance policy, contract, agreement or otherwise.

17. Insurance. To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, trustees, general partners, managing members, officers, employees, agents or fiduciaries of the Company or any other Enterprise, Indemnitee shall be covered by such policy or policies to the same extent as the most favorably-insured persons under such policy or policies in a comparable position.

18. Subrogation. In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

19. Services to the Company. Indemnitee agrees to serve as a director or officer of the Company or, at the request of the Company, as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of another Enterprise, for so long as Indemnitee is duly elected or appointed or until Indemnitee tenders his or her resignation or is removed from such position. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that any employment with the Company (or any of its subsidiaries or any

Enterprise) is at will, and Indemnitee may be discharged at any time for any reason, with or without cause, with or without notice, except as may be otherwise expressly provided in any executed, written employment contract between Indemnitee and the Company (or any of its subsidiaries or any Enterprise), any existing formal severance policies adopted by the Company's board of directors or, with respect to service as a director or officer of the Company, the Company's certificate of incorporation or bylaws or the DGCL. No such document shall be subject to any oral modification thereof.

20. Duration. This Agreement shall continue until and terminate upon the later of (a) ten years after the date that Indemnitee shall have ceased to serve as a director or officer of the Company or as a director, trustee, general partner, managing member, officer, employee, agent or fiduciary of any other Enterprise, as applicable; or (b) one year after the final termination of any Proceeding, including any appeal, then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to Section 12 of this Agreement relating thereto.

21. Successors. This Agreement shall be binding upon the Company and its successors and assigns, including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company, and shall inure to the benefit of Indemnitee and Indemnitee's heirs, executors and administrators.

22. Severability. Nothing in this Agreement is intended to require or shall be construed as requiring the Company to do or fail to do any act in violation of applicable law. The Company's inability, pursuant to court order or other applicable law, to perform its obligations under this Agreement shall not constitute a breach of this Agreement. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (i) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (ii) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (iii) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

23. Enforcement. The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as a director or officer of the Company.

24. Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; *provided*, *however*, that this Agreement is a supplement to and in furtherance of the Company's certificate of incorporation and bylaws and applicable law.

25. Modification and Waiver. No supplement, modification or amendment to this Agreement shall be binding unless executed in writing by the parties hereto. No amendment, alteration or repeal of this Agreement shall adversely affect any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his or her Corporate Status prior to such amendment, alteration or repeal. No waiver of any of the provisions of this Agreement shall constitute or be deemed a waiver of any other provision of this Agreement nor shall any waiver constitute a continuing waiver.

26. Notices. All notices and other communications required or permitted hereunder shall be in writing and shall be mailed by registered or certified mail, postage prepaid, sent by facsimile or electronic mail or otherwise delivered by hand, messenger or courier service addressed:

(a) if to Indemnitee, to Indemnitee's address, facsimile number or electronic mail address set forth below Indemnitee signature hereto; or

(b) if to the Company, to the attention of the Chief Executive Officer of the Company at Invivyd, Inc., 1601 Trapelo Road, Suite 178, Waltham, MA 02451, or at such other current address as the Company shall have furnished to Indemnitee, with a copy (which shall not constitute notice) to Jill Andersen, Chief Legal Officer, at Invivyd, Inc., 1601 Trapelo Road, Suite 178, Waltham, MA 02451.

Each such notice or other communication shall for all purposes of this Agreement be treated as effective or having been given (i) if delivered by hand, messenger or courier service, when delivered (or if sent *via* a nationally-recognized overnight courier service, freight prepaid, specifying next-business-day delivery, one business day after deposit with the courier), or (ii) if sent *via* mail, at the earlier of its receipt or five days after the same has been deposited in a regularly-maintained receptacle for the deposit of the United States mail, addressed and mailed as aforesaid, or (iii) if sent *via* facsimile, upon confirmation of facsimile transfer or, if sent *via* electronic mail, upon confirmation of delivery when directed to the relevant electronic mail address, if sent during normal business hours of the recipient, or if not sent during normal business hours of the recipient, then on the recipient's next business day.

27. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 12(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Delaware Court of Chancery, and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court of Chancery for purposes of any action or proceeding arising out of or in connection with this Agreement, (iii) appoint, to the extent such party is not otherwise subject to service of process in the State of Delaware, Capitol Services, Inc., Dover, Delaware as its agent in the State of Delaware as such party's agent for acceptance of legal process in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (iv) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court of Chancery, and (v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court of Chancery has been brought in an improper or inconvenient forum.

28. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. This Agreement may also be executed and delivered by facsimile signature and in counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

29. Captions. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

(*signature page follows*)

The parties are signing this Indemnification Agreement as of the date stated in the introductory sentence.

INVIVYD, INC.

(*Signature*)

(*Print name*)

(*Title*)

[INDEMNITEE]

(*Signature*)

(*Print name*)

(*Street address*)

(City, State and ZIP)

(*Signature page to Indemnification Agreement*)

Schedule of Material Differences to Exhibit 10.4

The following directors and executive officers are parties to an Indemnification Agreement with the Company, each of which are substantially identical in all material respects to the representative Indemnification Agreement filed herewith as Exhibit 10.4 except as to the name of the signatory and the date of each signatory's Indemnification Agreement. The name of each signatory is listed below. The actual Indemnification Agreements are omitted pursuant to Instruction 2 to Item 601 of Regulation S-K.

Indemnitee
Tamsin Berry
Marc Elia
David Hering, M.B.A.
Tom Heyman
Terry McGuire
Clive A. Meanwell, M.D.
Christine Lindenboom
Michael S. Wyzga
Jill Andersen
Frederick W. Driscoll
Jeremy Gowler
Peter Schmidt, M.D., M.S.
Tillman Gerngross
Jane Henderson
Rebecca Dabora

Exhibit 10.13

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[***]", HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

AMENDMENT NUMBER ONE

TO THE

COLLABORATION AGREEMENT

This Amendment Number One (this "**Amendment**"), dated November 18, 2022 (the "**Amendment One Effective Date**"), amends the **Collaboration Agreement** (the "**Agreement**") dated May 21, 2021 (the "**Effective Date**"), by and between **Adimab, LLC**, a Delaware limited liability company having an address at 7 Lucent Drive, Lebanon, NH 03766 ("**Adimab**") and **Invivyd, Inc.**, a Delaware corporation having an address at 1601 Trapelo Road, Suite 178, Waltham, MA 02451 ("**Invivyd**"), formerly known as **Adagio Therapeutics, Inc.** ("**Adagio**"). Capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Agreement. For clarity, "Invivyd" and "Adagio" refer to the same entity for purposes of this Agreement.

BACKGROUND

WHEREAS, Adimab has conducted and continues to conduct a series of [***] studies with respect to [***] and a funded discovery campaign with respect to [***] on behalf of Invivyd;

WHEREAS, the following manuscripts have been published or submitted for publication [***];

WHEREAS, during the course of [***], Adimab generated the sequences of numerous antibodies [***] and delivered them to Invivyd;

WHEREAS, Invivyd has filed certain Patents Covering [***];

WHEREAS, pursuant to Section 3.2(a)(i) of the Agreement, Invivyd exercised its Option for antibodies against COVID 19 [***];

WHEREAS, the [***] is expected to generate antibodies against [***] ([***] the "**Invivyd Funded Antibodies**") which may be Covered by Patents [***] ([***] the "**Invivyd Funded Antibody Patents**").

WHEREAS, the Parties wish to clarify certain rights and obligations related to the Invivyd Funded Antibodies and the Invivyd Funded Antibody Patents;

Now, Therefore, in consideration of the foregoing premises and the mutual covenants set forth below, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Adimab and Invivyd hereby agree as follows:

1. Clause (c) of Section 1.28 ("*Evaluation Term*") of the Agreement is hereby deleted in its entirety and replaced by the following:

   "(c) the disclosure by Invivyd of the sequence of any Program-Benefited Antibody (including via Patent prosecution), except with respect to [***],"

2. Section 1.64 ("*Program Antibody*") of the Agreement is hereby deleted in its entirety and replaced with the following:

   1.64 "**Program Antibody**" means each antibody that has the same sequence as an antibody (including a multispecific antibody) delivered by Adimab to Invivyd under a Research Program. It is understood and agreed that even if Adimab delivers sequences of Program Antibodies to Invivyd instead of protein samples, antibodies encoded by or containing such sequences are Program Antibodies, in addition to samples of which are physically delivered to Invivyd under this Agreement. For clarity, Program Antibodies include all Invivyd Funded Antibodies.

3. Section 1.65 ("*Program Antibody Patents*") of the Agreement is hereby deleted in its entirety and replaced with the following:

   1.65 "**Program Antibody Patents**" means, for a Target, Patents that (a) claim the composition of matter of, or the method of making or using, a Program-Benefited Antibody or any Product other than an Antigen Product and (b) do not Cover Adimab Platform Technology. For clarity, Program Antibody Patents include all Invivyd Funded Antibody Patents.

4. Section 3.2(a)(i) (*Option Exercise*) of the Agreement is hereby amended by inserting the following sentence at the end of this Section:

   "Notwithstanding anything to the contrary within this Agreement, disclosure of [***] shall not constitute designation of any of the antibodies within the Option exercised on September 13, 2022, without express written notice of such designation from Invivyd to Adimab and, for clarity, the other triggers contained in clauses (a), (b) and (d) of Section 1.28 ("*Evaluation Term*") shall continue to apply to [***]."

5. Section 3.2(a)(iii) (*Disclosed Antibody Sequences*) of the Agreement is hereby deleted in its entirety and replaced with the following:

   "(iii) Disclosed Antibody Sequences. (A) Neither Invivyd nor Adimab shall disclose the sequences of Program Antibodies or Program-Benefited Antibodies prior to the expiration of the Evaluation Term thereto without the prior written consent of the other Party, and Adimab shall not disclose the sequences of any Optioned Antibodies without the prior written consent of Invivyd. (B) Notwithstanding the provisions of Section 5.4(b) (*Program Antibody Patents*), in the event that Invivyd publicly discloses the sequences of one or more

Program Antibodies discovered in a Research Program (*e.g.*, through the publication of a Program Patent), other than [***], without the prior written consent of Adimab, then the Option will be deemed to have been exercised with respect to such Research Program, the Program Antibodies for which the sequences were disclosed will be Optioned Antibodies, and Invivyd will promptly pay the applicable Option Fee. For the avoidance of doubt, publication of sequences of [***] will not be deemed an exercise of the Option as to the disclosed antibody sequences, and will not trigger payment of the Option Fee and, for clarity, the other triggers contained in clauses (a), (b) and (d) of Section 1.28 ("*Evaluation Term*") shall continue to apply to [***]."

6. Section 5.4 (*Program Patent Prosecution and Maintenance*) of the Agreement is hereby amended by inserting the following new Section 5.4(b)(vii) ("*Mutual Right to Review Manuscripts for Publication*"):

"5.4(b)(vii) Mutual Right to Review Manuscripts for Publication. Adimab will have the right to review and comment on all Invivyd-sponsored or Invivyd-submitted [***] manuscripts that include an author with Adimab affiliation at the time of participation in the research that shall be the subject of any such proposed manuscript. Invivyd will have the right to review and comment on all Adimab-sponsored [***] manuscripts. The submitting Party shall deliver for review at least [***] prior to submission all such manuscripts intended to be submitted for publication. Neither Party shall submit such manuscript for publication without prior written approval by a representative of the other Party's [***] departments, which approval shall not be unreasonably withheld, but which approval shall be deemed to have been granted if the reviewing Party does not object to a planned publication at least [***] prior to the planned submission date as set forth in the request for approval. Nothing provided in this section shall affect the terms set forth in Section 3.2(a)(iii)(A)."

7. All other terms and conditions of the Agreement shall remain in full force and effect.

In Witness Whereof, the Parties have by duly authorized persons executed this Amendment as of the Amendment One Effective Date.

Invivyd, Inc.:	**Adimab, LLC:**
Sign: [***]	Sign: [***]
Print Name: [***]	Print Name: [***]
Title: [***]	Title: [***]

Exhibit 10.16

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[***]", HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

CONFIDENTIAL

AMENDMENT NO. 1 TO THE CELL LINE LICENSE AGREEMENT

THIS AMENDMENT NO. 1 TO THE CELL LINE LICENSE AGREEMENT (this "**Amendment**"), effective as of February 2, 2023 ("the **Amendment Effective Date**"), is entered and made by and between **WuXi Biologics (Hong Kong) Limited**, having an address at Flat/RM826, 8/F Ocean Centre Harbour City, 5 Canton Road TST, Hong Kong ("**WuXi Biologics**"), and Invivyd, Inc. having its principal place of business at 1601 Trapelo Road, Suite 178, Waltham, MA 02451 ("**Licensee**"). WuXi Biologics and Licensee may be referred to herein individually as a "**Party**" and collectively as the "**Parties**."

WHEREAS, Licensee was formerly known as "Adagio Therapeutics, Inc." with its principal place of business at 303 Wyman Street, Suite 300, Waltham, MA 02451; and

WHEREAS, WuXi Biologics and Licensee (then still known as Adagio Therapeutics, Inc.) entered into that certain Cell Line License Agreement, dated as of December 2, 2020 (the "**License Agreement**"); and

WHEREAS, as of September 13, 2022, Licensee changed its company name from "Adagio Therapeutics, Inc." to "Invivyd, Inc."; and

WHEREAS, the Parties now desire to amend the License Agreement as set forth herein.

NOW THEREFORE, in consideration of the mutual covenants and agreements contained herein below, the sufficiency of which is acknowledged by both Parties, the Parties agree as follows:

1. The table of [***] in Appendix I of the License Agreement is hereby deleted in its entirety and replaced with the following:

[***]

2. Licensee's contact information in Section 14.3 of the License Agreement is hereby deleted in its entirety and replaced with the following:

"To Licensee:

[***]"

3. Except as expressly amended by this Amendment, the License Agreement is and shall remain unchanged and in full force and effect in accordance with its terms and the Parties hereby ratify and reaffirm the License Agreement as amended hereby.

4. The laws of the State of New York, USA, without giving effect to principles of conflict of laws, govern all matters relating to this Amendment and the enforcement and interpretation thereof. Any dispute arising out of or in connection with this Amendment shall be resolved in accordance with Section 14.6 of the License Agreement.

5. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Each Party may rely on the delivery of executed electronic copies of counterpart execution pages of this Amendment and such electronic copies shall be legally effective to create a valid and binding agreement among the Parties

6. Any capitalized term used in this Amendment and not otherwise defined herein shall have the meaning given to that term in the License Agreement. This Amendment and the rights and obligations of the Parties hereto shall be governed, construed, and enforced in accordance with the governing law as stated in the License Agreement, and if no such governing law is specified therein, then with the laws of Hong Kong, without regard to the conflict of laws provision thereof.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed as of the Amendment Effective Date set forth above.

WuXi Biologics (Hong Kong) Limited	**Invivyd, Inc.**
By: [***]	By: [***]
Name: [***]	Name: [***]
Title: [***]	Title: [***]

Exhibit 10.17

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[***]", HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

MASTER SERVICES AGREEMENT

This Master Services Agreement (this "**Agreement**") is dated July 21, 2020 (the "**Effective Date**") and is between Adagio Therapeutics, Inc. ("**Client**"), with an address at 303 Wyman Street, Suite 300, Waltham, MA 02451, and WuXi Biologics (Hong Kong) Limited, with its registered address at Flat/RM826, 8/F Ocean Centre Harbour City, 5 Canton Road TST, Hong Kong ("**Provider**"), each of Client and Provider being a "**Party,**" and collectively the "**Parties**."

A. Client discovers and develops biologics and antibody treatments for infectious diseases.

B. Provider coordinates biologics development and manufacturing services including those provided by certain affiliated operating companies.

C. The Parties desire that one or more of Provider's affiliated operating companies provide services to Client on a project-by-project basis. The services for each project (the "**Services**") will be provided pursuant to separate and distinct contracts (each, a "**Work Order**") that automatically incorporate the terms of this Agreement.

The Parties therefore agree as follows:

1. DEFINITIONS

Terms defined elsewhere in this Agreement will have the meanings set forth therein for all purposes of this Agreement unless otherwise specified to the contrary. The following terms will have the meaning set forth below in this Article 1.

1.1 "**Affiliate**" of a Person means any other Person that directly or indirectly Controls, is Controlled by, or is under common Control with, the Person.

1.2 "**Applicable Law**" means all applicable laws, regulations, and other official guidelines and directives applicable to the Parties, their respective obligations under this Agreement (including relevant to the Services performed under this Agreement) or otherwise to Product (including the manufacturing, supply, use, transportation, marketing or sale of the Product), including cGMP.

1.3 "**Cell Line**" means a cell line that has been developed to produce a Product.

1.4 "**Certificate of Analysis**" means a certificate of analysis for testing of a Product in a form agreed to by the Parties.

1.5 “**cGMP**” means current Good Manufacturing Practices and General Biologics Products Standards as promulgated under the US Federal Food Drug and Cosmetic Act at 21 CFR (Chapters 210, 211, 600 and 610), the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under Directive 2001/83/EC (as amended by Directive 2004/27/EC), Directive 2003/94/EC and EudraLex – Volume 4 of the Rules Governing Medicinal Products in the European Union entitled "EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use", and ICH Guidance Q7A (Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

1.6 “**Confidential Information**” of a Party (the “**Disclosing Party**”) means all information and materials disclosed by or on behalf of the Party to the other Party (the “**Receiving Party”)** or its Personnel (as defined below) in connection with this Agreement, including all confidential, non-public, proprietary and/or trade secret information or materials owned or controlled by a Party, including technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, specifications, data, results and other material, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, other procedures related to the Services, and any tangible embodiments of any of the foregoing, and any scientific, manufacturing, marketing and business plans, any financial and personnel matters relating to a Party or its present or future products, sales, suppliers, customers, employees, investors or business. The Confidential Information of both Parties includes the existence, terms and objectives of this Agreement, and the nature of any dispute and the outcome of any arbitration proceedings arising out of or in connection with this Agreement. Without limiting the foregoing, the Product, Specifications, Client Materials, Client IP and Project IP are Client’s Confidential Information, as to which Client will be deemed the Disclosing Party and Provider will be deemed the Receiving Party in all circumstances and regardless of the Party initial disclosing the same. As between the Parties, Client shall solely own all of Client’s Confidential Information and Provider shall own all Provider’s Confidential Information.

Confidential Information excludes information that:

(a) at the time of disclosure to Receiving Party is in the public domain, other than as a result of a breach of an obligation of confidentiality or non-use or other misappropriation (including act or omission of Receiving Party);

(b) was known by Receiving Party prior to receipt from Disclosing Party, without restriction to confidentiality or use (as proven by Receiving Party’s written records);

(c) is disclosed to Receiving Party by a third party without an obligation of confidentiality and having the legal right to do so (as proven by Receiving Party’s written records); and

(d) is independently developed by Receiving Party without any benefit of or reference to, and not being derived or arising from, Confidential Information of the Disclosing Party (as proven by Receiving Party's written records).

1.7 "**Control**" over a Person means (a) owning fifty percent (50%) or more of the voting securities or other ownership interests of the Person or (b) having the power to direct the management or policies of the Person.

1.8 "**Intellectual Property**" means all legal rights in works, ideas or biological materials, including any patents and patent applications, trademarks and applications, trade names, service marks, domain names, copyrights and copyright applications and registrations, schematics, industrial models, inventions (whether patentable or not patentable), discoveries, improvements, know-how, show-how, trade secrets, computer software programs and all other intellectual property rights, including all applications and registrations with respect thereto, and all data, information (including intangible proprietary information and Confidential Information), reports and any related documentation.

1.9 "**Person**" means an individual, a corporation, a partnership, an association, a trust or other entity or organization, including a government or political subdivision or an agency thereof.

1.10 "**Personnel**" with respect to a Party, such Party's (a) employees, contractors, subcontractors, consultants, agents, Affiliates or persons otherwise associated with such Party as a result of the performance of this Agreement or a Work Order and (b) the employees, contractors, subcontractors, consultants, agents of such Party's Affiliates or persons otherwise associated with such Party's Affiliates as a result of the performance of this Agreement or a Work Order; provided, that one Party (and its employees, contractors, subcontractors, consultants, agents, Affiliates or persons otherwise associated with such Party) shall not be Personnel of the other Party.

1.11 "**Product**" means a Drug Substance, Drug Product, Master Cell Bank, Working Cell Bank, (each, as defined in the Quality Agreement), a part or derivative of the foregoing, proteins and antibodies, and any other deliverables produced or manufactured for Client pursuant to a Work Order, the Services or this Agreement, including that which is to be produced by a Cell Line.

2. SERVICES

2.1 **Work Orders**. Provider shall provide the Services to Client pursuant to each Work Order that is entered into during the term of this Agreement. The preferred form of Work Order is provided in Exhibit A. Each Work Order will automatically incorporate the terms of this Agreement and be a separate and distinct agreement. Work Order(s), when approved in writing by both Parties, shall be deemed an integral part hereof. Work Order(s) may be updated from time to time by mutual agreement. If there is a

contradiction between a provision of this Agreement and a Work Order, then the provision in this Agreement will take precedence unless the Work Order specifically states that it takes precedence over the provision.

2.2 **Manufacturing**. The manufacturing terms are provided in Exhibit B.

2.3 **Affiliates**.

(a) Provider may delegate or subcontract the Services, or any part thereof, to an Affiliate of Provider; provided, however, such Services must be performed at the facility indicated on the particular Work Order, unless otherwise agreed to by the parties. If the Services are provided by an Affiliate, then references to Provider in this Agreement will be deemed to be references to the Affiliate with the necessary modifications. Provider shall be liable for the performance of the Affiliate to the same extent as if the performance was that of Provider.

(b) An Affiliate of a Party may enter into a Work Order instead of the Party. If a Work Order is entered into by an Affiliate, then references to the Party in this Agreement will be deemed to be references to the Affiliate with the necessary modifications. The Party shall be liable for the performance of the Affiliate to the same extent as if the performance was that of the Party.

2.4 **Commercial Manufacturing Agreement**. It is understood and agreed that this Agreement governs the development, manufacture and supply of Product for development and clinical purposes. Accordingly, upon Client's request, Provider and Client shall enter into a mutually agreeable commercial manufacturing agreement whereby Provider will manufacture and supply Product to Client for commercial purposes.

3. CONTRACT PRICE; PAYMENT

3.1 **Contract Price:** Client shall pay Provider fees in the amount and manner provided in the applicable Work Order (the "**Contract Price**"). The Contract Price may be charged in accordance with a lump-sum or other pricing structure. The Contract Price will include service fees and, if applicable, an estimate for pass-through and raw materials costs.

3.2 **Expenses.** Client shall reimburse Provider for reasonable expenses that are (a) authorized by Client in writing, (b) described in the applicable Work Order, or (c) described in this Agreement, including Sections 4.5, 4.7, 5.1, 5.2, 5.3, 6.3, 7.3, 9.4, 12 and 13 and paragraphs 1.3 and 2.2 of **Exhibit B**.

3.3 **Milestones.** If a Work Order includes a payment for completion of a project stage or other milestone, then Provider shall notify Client promptly after the milestone is achieved. Client will be deemed to have agreed that the milestone was achieved unless it notifies Provider otherwise within [***] of receiving the notice. Each milestone

payment is designed to reflect the fair value of the corresponding Services, and is not dependent on any other milestone unless otherwise specified in the Work Order.

3.4 **Payment.** Client shall pay each undisputed portion of Provider's invoices within [***] of receipt by wire transfer to the account designated by Provider. All undisputed payments made under this Agreement and any Work Order will be made without set-off or other deduction of any nature. The Contract Price is exclusive of, and Client shall pay, any applicable taxes (other than taxes on Provider's income) and other fees of any nature imposed by or under the authority of any government authority.

3.5 **No Clawbacks.** The Contract Price and other payments under this Agreement and any applicable Work Order are non-cancelable and non-refundable; provided that Provider shall refund any undisputed pre-payments made for Services not performed.

3.6 **Payment Default.** In the event of an undisputed, overdue payment (a "**Payment Default**"), (a) interest of [***] will accrue daily ([***]) on the overdue payment as of the date of the Payment Default and (b) Provider may suspend the provision of the portion of the Services to which the Payment Default relates until the Payment Default is rectified by Client. If the Payment Default is not rectified within [***] after receipt of notice of such default by Client from Provider, then it will be deemed an incurable material breach of the applicable Work Order, and Provider may terminate the Work Order pursuant to Section 11.3.

3.7 **Annual Review.** At calendar year end, each party to a Work Order may propose a prospective adjustment of the Contract Price to reflect changes in pricing factors including foreign exchange fluctuation, cost reductions and efficiency increases, inflation or deflation and changes in the price of raw materials. The Parties shall negotiate in good faith with the aim of identifying a mutually acceptable amendment of the applicable Work Order.

4. PROVISION OF SERVICES

4.1 **Specifications.** Provider shall provide the Services in accordance with the Specifications in the applicable Work Order.

4.2 **Qualifications.** Provider shall ensure that its Personnel (a) have the appropriate skills, training and experience to perform the Services and (b) are bound by confidentiality obligations consistent with the terms of this Agreement.

4.3 **Compliance.** Provider shall provide the Services in a professional and workmanlike manner and in compliance with generally accepted industry practices and the standards and the terms of this Agreement, the applicable Work Order, the Quality Agreement, Applicable Law and applicable Good Practice (GxP) guidelines in all material respects.

4.4 **Timing.** The timing of the applicable Services and provision of the deliverables and Work Product as set forth in the applicable Work Order is critical to Client and Provider's understanding that time is of the essence and Provider's assurances that it is able to meet the timelines and provide the deliverables and Work Product as set forth in a particular Work Order was a significant inducement for Client to enter into this Agreement. Provider shall use all reasonable and adequate safety and protection measures to ensure that any such timelines set forth in a particular Work Order are achieved and that the results of the Services are not endangered by any interruption due to Provider's fault. Provider will promptly notify Client of any delays that arise during the performance of a Work Order.

4.5 **On-Site Monitoring.** Representatives of Client may, upon reasonable notice and at times reasonably acceptable to Provider, visit the facilities where the Services are provided and consult informally during such visits with appropriate Personnel in order to monitor the Services. The representatives will be bound by rules applicable to the facilities and may, at the reasonable discretion of Provider, be prohibited from entering or only given limited access to certain areas within the facilities. Provider may require that Client or the representatives execute an agreement that regulates the representatives' conduct during its visit. Client shall be responsible for all expenses incurred in connection with such visits, and all its personnel must be subject to the same level of confidentiality as in this Agreement.

4.6 **Audits of Premises**. At agreed-upon dates and times**,** Client shall have the right, acting reasonably and at its expense, and no more than once in any given [***] period, except for cause, during the term of this Agreement hereof, to inspect and audit the premises and quality system used by Provider to assure compliance with this Agreement, other prevailing quality system requirements, and Applicable Law. Such audit shall be limited to those portions of or areas within the applicable premises that are involved in performance of the Services including manufacturing suites and other related areas supporting production of Product (e.g., warehouse, water systems, storage, buffer and media prep), and shall be conducted in a manner so as to minimize disruption of business operations. Client shall have the right to appoint an appropriately qualified third party selected by Client and reasonably acceptable to Provider to conduct the audit. Client may initiate a "for cause" audit based on a specific Product quality-impacting event occurring during the Services. Timing of such audit will be commensurate with the type and severity of such quality-impacting event, but in any case within [***] after receipt of the audit agenda by Provider.

4.7 **Regulatory Inspections.** Provider will permit visits and/or inspections by regulatory authorities of any country as required by Applicable Law, and will permit Client or its agents to be present and participate in any visit or inspection by such regulatory authority of the facility (to the extent it relates in any way to any Product or the Services) or the manufacturing process. Provider will give as much advance notice as possible to Client of any such visit or inspection. Provider will provide Client with a copy

of any report or other written communication received from such authority in connection with such visit or inspection, and any written communication received from any regulatory authority relating to the Product, the Services, the facility (if it relates to or affects the development and/or manufacture of Product or the provision of the Services) or the manufacturing process, within [***] after receipt, and will consult with, and seek approval from, Client before responding to each such communication if time permits. Provider will provide Client with a copy of its final responses within [***] after submission. Client will pay Provider a daily fee to cover the cost of regulatory inspection specific to Product under this Agreement.

5. SOURCING OF MATERIAL

5.1 **Materials.** Provider shall, at Client's expense or as otherwise specified in the applicable Work Order, purchase all materials necessary for the Services (the "**Materials**"). If a Material is not commercially available, then Client may elect to (a) supply, at its expense, the Material to Provider; or (b) amend the applicable Work Order to permit the use of a commercially available substitute. Provider shall perform the market research and propose a list of vendors in compliance with Applicable Law and applicable GxP in all material respects. Provider shall take the inventory risk of the selected materials, such as the damages to pass through materials caused by improper storage or pollutions.

5.2 **Client Materials.** If a Material is to be supplied by Client (a "**Client Material**"), then Client shall provide the Client Material at its expense in a timely manner and provide such information as may be required by Provider or Applicable Law concerning the stability, storage and safety requirements of the Client Material. Without limiting the foregoing, all cell banks, amino acid sequences, DNA sequence, proteins and antibodies, and other materials, including all copies or derivatives thereof, provided by Client to Provider are Client Materials. All Client Materials shall remain the exclusive property of Client. Provider shall ensure that the Client Material will be (a) used solely for the purpose of providing the Services, (b) only distributed to Personnel on a need-to-know basis for the provision of the Services and (c) preserved and protected in a manner consistent with the specifications listed in the applicable Work Order and any relevant standard operating procedures or other written instructions provided by Client. Unless there are any modifications to Client Materials upon Client's prior approval solely for the purpose of providing the Services under this Agreement, Provider shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of any Client Materials, including analyzing the Client Materials by physical, chemical or biochemical means. ANY MATERIALS PROVIDED BY CLIENT HEREUNDER (INCLUDING CLIENT MATERIALS) ARE PROVIDED WITHOUT REPRESENTATION OR WARRANTY OF ANY SORT, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, INCLUDING ANY REPRESENTATION OR WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE,

AND CLIENT MAKES NO REPRESENTATION THAT THE USE OF SUCH MATERIALS WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT OF ANY THIRD PARTY.

5.3 **Unused Client Materials and Other Materials.** Provider shall, at Client's option and expense, return, destroy or otherwise dispose of unused Client Materials promptly after the earlier of (a) completion of the Services for which the Client Materials were provided, (b) termination of the applicable Work Order, or (c) receipt of written instructions from Client pertaining to its disposition. If the Client Materials are to be destroyed or otherwise disposed of, then Provider shall give [***] notice to Client prior to destruction or other disposition, and Client may instead elect during such [***] period to have the Client Materials transferred to Client. If Client fails to respond within [***], then Provider may dispose it at its own discretion. Provider may dispose of other unused Materials (i.e. other than Client Materials) at its sole discretion; provided that if Client has paid for such other Materials, then they will be treated as Client Materials for purposes of this Section 5.3.

6. RECORDS

6.1 **Storage for Records.** All materials, data and documentation obtained or generated by Provider in the course of providing the Services, including all computerized records and files ("**Records**"), will be maintained in a secure area in accordance with industry standards. The Records are the sole and exclusive property of Client.

6.2 **Retention of Records.** Upon termination of the applicable Work Order, Provider shall, at Client's option, (a) destroy the Records, (b) deliver the Records to Client, or (c) retain the Records for [***] and then destroy the Records. If the Records are to be destroyed, then Provider shall give [***] notice to Client, and Client may elect during such [***] period to have the Records transferred to Client. Notwithstanding the foregoing, the Records shall be retained as required by Applicable Law or as otherwise necessary for regulatory or insurance purposes.

6.3 **Storage for Product.** All the Products shall be stored in Provider's facilities for [***] free of charge, and a reasonable monthly storage fee for Products shall be charged after the [***] period. Client agrees that the commercial value and/or cost of replacement or remanufacture of any Products provided to Provider for storage is a matter that, as between Client and Provider, is within the sole and exclusive knowledge of Client. Client agrees that it is responsible for insuring such items against damage or loss and shall purchase appropriate insurance to cover its Products stored in Provider's facilities. Client further agrees and acknowledges that under no circumstances shall Provider be liable for loss or damage to any such items, in an amount that exceeds the aggregate fees paid to Provider for storage services of such items. Transportation of Product by Provider on behalf of Client shall be made at the sole risk and expense of Client, notwithstanding the use of any INCOTERMS delivery term on any waybill or other documentation relating to the transportation. Provider shall not be liable for the actions or omission of any delivery services or carriers or freight forwarders.

7. INTELLECTUAL PROPERTY

7.1 Ownership

(a) Except as otherwise provided in this Agreement, (i) Provider has no right, title or interest in or to any Intellectual Property that is owned or controlled by Client or any of its Affiliates prior to the Effective Date (including licensed by any third party to Client, or any of its Affiliates) or developed or obtained independently of this Agreement ("**Client IP**") and (ii) Client has no right, title or interest in or to any Intellectual Property that is owned or controlled by Provider or any of its Affiliates prior to the Effective Date (including licensed by any third party to Provider, or any of its Affiliates) or developed or obtained independently of this Agreement (**"Provider IP**").

(b) Client shall own all right, title and interest in and to any and all Intellectual Property, data and results created, developed, invented, first reduced to practice or made, by Provider or Personnel, solely or jointly with Client or others in connection with the provision of the Services, including any development, improvement, modification, addition, adaptation, enhancement, derivative, variant or progeny to or of any Product, Client Materials, Client's Confidential Information or Client IP or related to any of the foregoing ("**Project IP**"), including any and all Intellectual Property rights inherent therein and appurtenant thereto. Client agrees that Project IP does not include Intellectual Property created or developed in connection with the provision of the Services that (i) relates to experimental methods, (ii) relates to manufacturing processes developed at Provider's expense, or (iii) constitutes Provider IP or derivatives thereof developed by Provider through the performance of the Services, provided, that such derivatives (a) are made without the benefit of Client IP, Client Materials and/or Client's Confidential Information, and (b) could have been developed without performance of the Services (i.e., in the event that unique aspects of the Services and/or Client IP, Client Materials or Client's Confidential Information were not a "but for" cause of such derivative) ("**Manufacturing Improvements**").

(c) Provider hereby assigns and shall assign (and require its Affiliates to assign) all right, title and interest in Project IP (including any and all Intellectual Property rights therein and appurtenant thereto) to Client. Provider shall ensure that each of the Personnel vests in Provider, or its Affiliate, as applicable, any and all rights, title and interest that such person(s) might otherwise have in and to the Project IP (including any and all Intellectual Property rights therein and appurtenant thereto). Provider shall execute, and shall require its Personnel, to execute, any documents reasonably required to confirm Client's ownership of the Project IP, and any documents required to apply for, maintain and

enforce any patent or other right in the Project IP. Client shall promptly notify Provider of any patents granted for Project IP.

(d) Provider will be responsible for all payments to be made to Personnel of Provider and its Affiliates in accordance with any Applicable Law requiring remuneration for inventions.

7.2 **General Licenses**

(a) Client hereby grants, and shall ensure that each applicable Affiliate will promptly grant, to Provider and its Affiliates the limited right to use Client IP and Project IP for the purpose of providing the Services.

(b) To the extent any Manufacturing Improvements or other Provider IP are necessary to exploit deliverables provided hereunder or manufacture Product ("**Necessary IP**"), Provider hereby grants, and shall ensure that each applicable Affiliate will promptly grant, to Client and its applicable Affiliates a non-exclusive, worldwide, fully paid-up, irrevocable, transferable license, including the right to grant sublicenses, under, in and to Necessary IP to develop, conduct clinical trials for, formulate, manufacture, test, label, package, seek Regulatory Approval for, market, commercialize, make, have made, use, sell import and export Product.

(c) To the extent any Manufacturing Improvements or other Provider IP (including the [***] referred to in Section 7.5) are not necessary to exploit deliverables provided hereunder or manufacture Product ("**Optional IP**"), Provider shall notify Client thereof before embedding or incorporating such Optional IP into any deliverable provided hereunder or the manufacture of Product. To the extent Client consents to having any such Optional IP be incorporated into any deliverable provided hereunder or the manufacture of Product, upon Client's request, Provider may grant to Client and its applicable Affiliates a non-exclusive, worldwide, irrevocable, transferable license, including the right to grant sublicenses, under, in and to such Optional IP to develop, conduct clinical trials for, formulate, manufacture, test, label, package, seek Regulatory Approval for, market, commercialize, make, have made, use, sell import and export Product. Provider and Client shall enter into a mutually agreeable license agreement to grant Client the right to use such Optional IP; provided that the license granted therein shall be no less restrictive than the one set forth in this Section 7.2(c). Without limiting the foregoing, should Provider incorporate Optional IP into any deliverable provided hereunder or the manufacture of Product without first notifying and gaining Client's consent, such Optional IP shall be treated as Necessary IP and become subject to the license grant in Section 7.2(b).

7.3 **Prosecution, Maintenance and Enforcement of Patents.**

(a) Client will, at its own expense, have sole control of filing and prosecuting applications for, and maintenance and enforcement of patent applications and patents claiming Project IP. Provider will, at Client's expense, use reasonable efforts to assist Client to obtain, maintain and enforce such patents, including cooperating with Client in Client's activities to file, prosecute and maintain patent applications and patents claiming Project IP and, upon Client's request, reviewing and providing comments to Client relating to such patent applications and patents.

(b) Except to the extent required to protect Provider IP, Manufacturing Improvements, Necessary IP or Optional IP rights, and without limiting Sections 7.2(b), or 7.2(c), Provider and its Affiliates hereby covenant and agree not to, alone or in cooperation with any third party, sue or bring any cause of action against Client, its Personnel, suppliers, distributors, salespersons, customers, licensees or end-users for any patent infringement based on any development, manufacturing or commercialization activities relating to the Product conducted by Client or any third party for Client. This covenant will run with and attach to any and all patent rights owned or controlled, in whole or in part, by Provider and shall be binding upon any assignee or sublicensee of any Intellectual Property from Provider.

(c) Provider agrees that (i) it will not publish or publicly present the results of any data or other information generated from the activities hereunder that includes or consists of Client's Confidential Information, Client Materials or Client IP without Client's prior written consent, and (ii) it will at no time file or have filed any patent application or initiate any procedure purporting to obtain any legal rights covering any discovery or inventions that would infringe Project IP or that it first develops, conceives, invents, reduces to practice or makes while using Client's Confidential Information or Client Materials, without Client's prior written consent.

7.4 **Technology Transfer.** Subject to compliance with the terms and conditions of this Agreement, Client may request transfer for the Product for an alternative or second-source manufacturing. Subject to Client and Provider agreeing to commercially reasonable terms that have been negotiated in good faith on the scope and duration of the technology transfer, such agreement shall be set out in a separate Work Order and at Client's expense, Provider shall provide the technology transfer reasonably necessary for properly skilled personnel of Client or Client's Affiliate, to manufacture and release Product. The technology transfer will include all protocols, batch records, test methods, data, results and Specifications necessary to establish manufacturing of the Product, and will include the cell line and cell banks, subject to a license and License Agreement. Client shall be liable for the costs of such technology transfer.

7.5 [***] **License.** If Client [***] for the manufacture of Product, then Client shall purchase from Provider a [***]. [***].

8. REPRESENTATIONS AND WARRANTIES

8.1 **Mutual.** Each Party represents and warrants that (a) it validly exists under the laws of the jurisdiction in which it was organized, (b) it has the full power, right and authority to execute and deliver this Agreement and to perform its obligations under this Agreement, (c) this Agreement once executed will constitute a legal, valid and binding agreement enforceable against it and (d) its performance of this Agreement will not conflict with any obligations it may have to any other person.

8.2 **By Provider**. Provider hereby represents, warrants and covenants to Client that:

(a) the Product released to Client conforms to the Specifications agreed by both Parties, has been and shall be the subject of Services performed in accordance with this Agreement, the applicable Scope of Work, the Quality Agreement, unless otherwise waived in writing by Client, and all Applicable Laws; and is and will be free and clear of all liens and encumbrances;

(b) the operation of the facility(ies) where Services are performed are and will continue to be in compliance with all Applicable Laws (including the receipt and possession of all applicable licenses, permits, registrations and authorizations);

(c) it has maintained and will continue to maintain, in accordance with and for the period required under this Agreement, the applicable Work Order, the Quality Agreement, and all Applicable Laws, complete and adequate records pertaining to the Services, Products, methods and the facility(ies) used in the performance of this Agreement;

(d) it will not enter into any agreement or arrangement with any party which will hinder it or prevent it from performing its obligations under this Agreement; and

(e) it has the capacity to produce the Product in accordance with the timeframes set forth in the Work Orders and shall maintain such capacity in the event the Parties enter into an agreement for commercial supply of Product.

8.3 **Infringement.** Each Party represents and warrants that, to the best of its knowledge, the Services will not infringe the Intellectual Property rights of any third party.

8.4 **Debarment.** (a) Provider represents and warrants that neither it nor any of the Personnel; and (b) Client represents and warrants that none of its employees or agents involved in developing or commercializing any Product, in each case of (a) and (b), has been debarred, or, to the best of its knowledge, is under consideration for debarment,

by the United States Food and Drug Administration from working in or providing services to any pharmaceutical or biotechnology company pursuant to the Generic Drug Enforcement Act of 1992 or any other governmental authority pursuant to analogous laws. Each Party shall immediately notify the other Party upon becoming aware of a breach of this Section 8.4.

8.5 **Compliance with Law.** Each Party (a) represents and warrants that neither it nor any of its Affiliates violated any Applicable Law in connection with actions leading up to entry into this Agreement or any Work Order and (b) shall, and shall ensure that each applicable Affiliate will, comply with all Applicable Law in connection with performance of this Agreement and any Work Orders. Each Party shall immediately notify the other Party upon becoming aware of a breach of this Section 8.5. Breach of this Section 8.5 with respect to the U.S. Foreign Corrupt Practices Act or any other anti-bribery law will be deemed an incurable material breach for purposes of Section 11.3.

9. INDEMNIFICATION; LIMITATION ON LIABILITY; INSURANCE

9.1 **Third Party Claims Against Client.** Provider shall defend, indemnify and hold Client and its Affiliates and its and their directors, officers, employees, agents and consultants and legal, financial, accounting and other advisors ("**Related Persons**") harmless from and against any and all liabilities and damages (including reasonable attorneys' fees) ("**Losses**") resulting from any third party claims, demands, suits or proceedings ("**Claims**") to the extent arising out of or relating to (a) its performance of the Services, (b) a breach of this Agreement by Provider or any of its Related Persons, (c) a violation of Applicable Law by Provider or any of its Related Persons, or (d) the negligence, recklessness or willful misconduct of Provider or any of its Related Persons during the course of activities carried out in connection with this Agreement. The indemnification obligations set forth in this Section 9.1 do not apply to the extent that the Loss or Claim arises in whole or in part from the negligence, recklessness or willful misconduct of Client or any of its Related Persons or a breach of this Agreement by Client or any of its Related Persons.

9.2 **Third Party Claims Against Provider.** Client shall defend, indemnify and hold Provider and its Related Persons harmless from and against any and all Losses resulting from any Claims to the extent arising out of or relating to (a) either party's use of Project IP or deliverables provided or produced under a Work Order (including inappropriate use of any license under Provider IP by Client) and Provider's use of Client Material in accordance with their specifications, (b) a breach of this Agreement by Client or any of its Related Persons, (c) a violation of Applicable Law by Client or any of its Related Persons, (d) the negligence, recklessness or willful misconduct of Client or any of its Related Persons during the course of activities carried out in connection with this Agreement, or (e) development or manufacture (except by Provider under this Agreement), use, handling, storage, or other disposition of Products by or on behalf of Client or any of its Affiliates, sublicensees, agents or contractors, including Claims and

threatened Claims based on product liability, bodily injury, risk of bodily injury, death or property damage or the failure to comply with any Applicable Law. The indemnification obligations set forth in this Section 9.2 do not apply to the extent that the Loss or Claim arises in whole or in part from the negligence, recklessness or willful misconduct of Provider or any of its Related Persons or breach of this Agreement by Provider or any of its Related Persons.

9.3 **Intellectual Property Claims**. Client shall defend, indemnify and hold Provider and its Related Persons harmless from and against Losses resulting from Claims arising out of or related to infringement of any Intellectual Property rights relating to the Services or the Product other than Claims to the extent based on Provider IP or Necessary IP that is used in the Services. Provider shall defend, indemnify and hold Client and its Related Persons harmless from and against Losses resulting from Claims arising out of or related to infringement of any Intellectual Property rights related to the Services to the extent based on the use of the Provider IP.

9.4 **Defense**. Each Party shall notify the other Party promptly upon learning of a Claim that is subject to indemnification pursuant to Sections 9.1, 9.2, or 9.3. The indemnifying Party may control, at its own expense, the defense of the Claim in good faith with counsel of its choice as long as such counsel is reasonably acceptable to the indemnified Party. The indemnified Party shall use reasonable efforts to cooperate in the defense and may participate at its own expense using its own counsel. No compromise or settlement of any Claim may be made by the indemnifying Party without the indemnified Party's written consent unless (a) there is no finding or admission of any violation of law or any violation of the rights of any person and no effect on any other claims that may be made against the indemnified Party, (b) the sole relief provided is monetary damages that are paid in full by the indemnifying Party and (c) the indemnified Party's rights under this Agreement are not adversely affected.

9.5 **Limitations on Liability.**

(a) EXCEPT FOR LOSSES ARISING FROM BREACHES OF ARTICLES 7 OR 10, FROM THE INDEMNIFICATION OBLIGATIONS UNDER SECTIONS 9.1, 9.2, OR 9.3, OR FROM A PARTY'S GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, NEITHER PARTY WILL BE LIABLE TO THE OTHER PARTY FOR ANY PUNITIVE, MULTIPLE, LIQUIDATED, SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT (OR THE TERMINATION HEREOF), INCLUDING LOSS OF PROFITS OR ANTICIPATED SALES.

(b) Except for Losses arising from breaches of Articles 7 or 10, Provider's maximum aggregate total liability in connection with this Agreement (including any related applicable Work Orders) will not exceed the total payments actually paid by Client under the related applicable Work Order.

9.6 **Insurance.** Each Party shall ensure that insurance coverage is carried and maintained with a financially sound and reputable insurer against loss from such risks and in such amounts as is (a) sufficient to support its obligations under this Agreement and any Work Order and (b) customary in the industry to support such obligations for similarly situation companies performing similar obligations. Each Party shall provide a copy of the applicable insurance policy if requested by the other Party.

10. CONFIDENTIALITY AND PUBLICITY

10.1 **Confidentiality; Disclosure and Use Restrictions.** The Receiving Party shall, and shall ensure that it and its Personnel (a) maintain the Confidential Information of the Disclosing Party in confidence and (b) not disclose, transfer or use the Confidential Information of the Disclosing Party for any purpose other than in connection with and as expressly permitted under this Agreement. Each Receiving Party agrees to (i) institute and maintain reasonable and customary security procedures to identify, protect and account for all copies of Confidential Information of the Disclosing Party, and (ii) limit disclosure of the Disclosing Party's Confidential Information to its Personnel that have a need to know such Confidential Information for purposes of the Receiving Party exercising its rights and performing its obligations under this Agreement; provided that such Personnel are informed of the confidential nature of the information, and are subject to obligations of confidentiality, non-disclosure, non-use and inventions similar to and at least as restrictive as those set forth in this Agreement. The Receiving Party shall notify the owning Party as promptly as practicable of any unauthorized use or disclosure of the Confidential Information, but in any event no later than [***] thereafter; provided, that, for clarity, such notification shall not excuse the Receiving Party from any liability in connection with such unauthorized use or disclosure.

10.2 **Required Disclosures**. If a duly constituted government authority, court or regulatory agency orders that a Party hereto disclose information with respect to which it is subject to an obligation of confidentiality under this Agreement, such Party shall comply with the order, but shall (a) give prompt written notice to the Disclosing Party of the proposed disclosure, and allow the Disclosing Party at least [***] to object to all or any portion of the disclosure before it is disclosed; (b) if advance notice is not possible, provide written notice of disclosure immediately thereafter; (c) to the extent possible, narrow the scope of the required disclosure; and (d) use reasonable efforts to secure confidential treatment of such information prior to its disclosure (whether through protective orders or otherwise), it being understood that any information so disclosed shall otherwise remain subject to the limitations on use and disclosure hereunder. The Party permitted to disclose any Confidential Information under this Section 10.2 shall take into consideration all comments and objections raised by the other Party. The Party permitted to disclose any Confidential Information under this Section 10.2 shall further cooperate with and provide the other Party with the opportunity to seek any protective order reasonably deemed necessary by such Party.

10.3 **Return of Confidential Information.** Upon termination of this Agreement, or upon earlier request by the Disclosing Party, Receiving Party shall cause all Confidential Information of the Disclosing Party to be promptly destroyed or returned to the Disclosing Party (at Disclosing Party's request); provided, however, that the Receiving Party may retain (a) a single secure copy of any Confidential Information for legal archival purposes, and (b) electronic back-up files that have been created by routine archiving and back-up procedures need not be deleted.

10.4 **Audits.** Provider and its Affiliates may have in the past provided, and may currently or in the future provide, services to other customers that are similar to the Services. Provider is absolutely committed to protecting its customers' Intellectual Property, and shall not use the Intellectual Property of a customer for the benefit of any person other than that customer. In order to protect the Confidential Information of Client and the confidential information of other customers, Provider shall use reasonable efforts to ensure that other customers do not seek the disclosure of Confidential Information of Client, and Client hereby agrees it shall not seek the disclosure of confidential information of other customers of Provider. Notwithstanding the foregoing, if Client wishes to conduct an audit that relates to services provided to another customer for purposes of confirming that Client's Intellectual Property is adequately protected, then Provider shall use reasonable efforts to seek the other customer's approval to waive confidentiality obligations to the extent necessary to allow Client to conduct the audit in a manner that does not involve disclosure of the other customer's confidential information to Client. If another customer wishes to conduct an audit that relates to the Services for purposes of confirming that the other customer's Intellectual Property is adequately protected, then Client shall waive Provider's confidentiality obligations to Client to the extent necessary to allow the other customer to conduct the audit in a manner that does not involve disclosure of Client's Confidential Information to the other customer. Such audits may involve an independent auditor designated by Provider and paid for by the person seeking the audit.

10.5 **Publicity.** Each Party shall not, and shall ensure that its Personnel will not, use the name, symbols or marks of the other Party or any of its Affiliates in any advertising or publicity material or make any form of representation or statement that would constitute an express or implied endorsement by the other Party or any of its Affiliates of any commercial product or service, without the other Party's or Affiliate's prior written consent. Neither Party shall disclose to any third party nor to the public generally (a) the terms of this Agreement, or (b) the specific relationship between the Parties established hereunder, except where such disclosure is necessary for regulatory approval of Product. Notwithstanding the foregoing, the Parties shall have the right to disclose the material commercial terms of this Agreement in connection with a bona fide potential financing, acquisition or commercial arrangement; provided, however, that prior to any such disclosure, such Party (i) shall require the intended recipient to sign an undertaking agreeing to accord confidential treatment to such information at least as restrictive as the terms set forth herein and not use such information except to

evaluate the proposed acquisition, financing or commercial arrangement, and (ii) shall take such other steps reasonably necessary to secure confidential treatment of such information.

10.6 **No Representation or Warranty.** It is understood and acknowledged by the Receiving Party that in providing the Confidential Information to the Receiving Party, the Disclosing Party make no representation or warranty as to the accuracy or completeness of the Confidential Information or any part thereof, and the Disclosing Party shall not be liable for any errors or omissions for any damages, or otherwise in any manner, relating to any Confidential Information or other information furnished or not furnished pursuant to this Agreement or resulting from any use of any such information. The Receiving Party shall rely solely on their own investigations, interpretations and analyses.

11. TERM AND TERMINATION

11.1 **Term.**

(a) The term of this Agreement commences on the Effective Date and, unless terminated earlier in accordance with this Agreement, expires upon the completion of the Services.

(b) Unless terminated earlier in accordance with this Agreement, the term of each Work Order commences on the date indicated in the Work Order and will terminate upon completion of the Services. For clarity, Work Orders are separate and distinct contracts that automatically incorporate the terms of this Agreement, and are not affected by the termination of this Agreement.

11.2 **Termination for Convenience.** Either Party may terminate this Agreement at any time with [***] advance notice to the other Party; provided that to the extent an executed Work Order has a term that is longer than such termination, this Agreement will remain in force and effect with respect to such Work Order until the expiration of such Work Order or completion of the Services under such Work Order. Any outstanding Work Order may be separately terminated upon agreement by the Parties or for cause in accordance with Section 11.3.

11.3 **Termination for Breach.** Either Party may terminate this Agreement or a Work Order immediately upon notice to the other Party if (i) a material breach of this Agreement or the applicable Work Order by the other Party remains uncured [***] after notice of the material breach was received by the other Party and (ii) the material breach was not caused by the Party terminating this Agreement or the applicable Work Order or any of its Affiliates.

11.4 **Survival.** Upon termination of this Agreement or a Work Order, all outstanding rights and obligations between the Parties arising out of or in connection with this Agreement

or the Work Order, as the case may be, will immediately terminate, other than any obligations and rights that (a) matured prior to the effective date of the termination or (b) by its nature are intended to survive, including, but not limited to, Articles 1 (to the extent needed to interpret surviving provisions or Work Orders), 5 (with respect to Work Orders), 6, 7, 9, 10, 12 (with respect to Work Orders) and 14 and Sections 11.3 (with respect to Work Orders), 11.4 and 11.5 (with respect to Work Orders). For the avoidance of doubt, the terms of this Agreement are automatically incorporated into a Work Order and shall survive the termination of this Agreement.

11.5 **Termination Fee.**

If a Work Order is terminated early by Client under Section 11.2 then Client shall pay Provider for the Services rendered and all non-cancelable obligations in connection with the Services.

(a) If non-manufacturing Services are terminated by Provider due to Client's material breach pursuant to Section 11.3, then Provider may charge Client a termination fee equal to [***] of the remaining value of the non-manufacturing Services within the Work Order as non-exclusive liquidated damages in connection with the redeployment of reserved Personnel and administrative overhead and costs.

(b) If manufacturing services are terminated by Provider due to Client request or material breach, Client may be charged cancellation fees as specified in Article 12.

12. CANCELLATION TERMS FOR MANUFACTURING SERVICES

12.1 **Cancellation of non-GMP Manufacturing.** If a notice to cancel non-GMP manufacturing in an executed Work Order and/or this Agreement is received from Client, Provider will make reasonable efforts to find an alternative customer to fill the manufacturing slot. In the case where no alternative customer can be identified to fill the slot(s), charges for terminating or cancelling the related work under this Agreement ("**Cancellation Charge(s)**") will be applied based on the following:

(a) No Cancellation Charge except cost of non-cancellable raw materials that cannot otherwise be used by Provider, purchased by Provider for purposes of development and production under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received at least [***] before the scheduled vial thaw;

(b) [***] of a non-GMP batch fee plus cost of non-cancellable raw materials that cannot otherwise be used by Provider, purchased by Provider for purposes of development and production under the applicable Work Order and/or this

Agreement (as the case may be), if the cancellation notice is received [***] to [***] before the scheduled vial thaw;

(c) [***] of a non-GMP batch fee plus cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of development and production under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received [***] to [***] before the scheduled vial thaw;

(d) [***] of a non-GMP batch fee plus cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of development and production under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received within [***] prior to the scheduled vial thaw;

(e) [***] of a non-GMP batch fee plus cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of development and production under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received after vial thaw but before the bioreactor inoculation; and

(f) [***] of a non-GMP batch fee plus cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of development and production under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received after the bioreactor inoculation.

12.2 **Cancellations for cGMP Drug Substance Manufacture.** If a notice to cancel a cGMP manufacturing run is received from Client, Provider will use commercially reasonable efforts to find an alternative customer (but excluding any customer or project under existing contract with Provider) for the manufacturing slot. In the case where no alterative customer can be identified to fill the slot(s), Cancellation Charge(s) will be applied based on the following:

(a) No Cancellation Charge except the cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of cGMP manufacture under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received greater than [***] before the scheduled vial thaw;

(b) [***] of the cGMP manufacturing run fee plus cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of the cGMP manufacture under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received between [***] and [***] before the scheduled vial thaw; and

(c) [***] of a cGMP manufacturing run fee plus cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of cGMP manufacture under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received within [***] before the scheduled vial thaw or anytime thereafter.

12.3 **Cancellation for cGMP Drug Product Manufacture.** If a notice to cancel a cGMP Drug Product manufacturing run is received from Client, Provider will use commercially reasonable efforts to find an alternative customer (but excluding any customer or project under existing contract with Provider) to fill the manufacturing slot(s). In the case where no alterative customer can be identified to fill the slot(s), Cancellation Charge(s) will be applied based on the following:

(a) [***], except the cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of the cGMP Drug Product manufacture under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received greater than [***] before the scheduled cGMP Drug Product manufacturing run;

(b) [***] of the cGMP Drug Product manufacturing run fee plus cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of the cGMP Drug Product manufacture under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received between [***] and [***] days before the scheduled cGMP Drug Product manufacturing run; and

(c) [***] of the cGMP Drug Product manufacturing run fee plus cost of non-cancellable raw materials that cannot otherwise be used by Provider purchased by Provider for purposes of the cGMP Drug Product manufacture under the applicable Work Order and/or this Agreement (as the case may be), if the cancellation notice is received within [***] before the scheduled GMP Drug Product manufacturing run or anytime thereafter.

13. SHIPPING

13.1 All materials to be provided by Provider to Client will be delivered FCA (carrier named by Client) (Incoterms 2020), including Product and other deliverables produced under a Work Order, returned Client Materials, returned Records and returned Confidential Information. For the avoidance of doubt, FCA (carrier named by Client) means Provider is responsible for handing over the materials, cleared for export, to a carrier named by Client. Client assumes risk at hand over and pays all costs.

13.2 All materials to be provided by Client to Provider will be delivered DDP (site designated by Provider) (Incoterms 2020), including Client Materials. For the avoidance of doubt, DDP (site designated by Provider) means Client is responsible for delivery to and

unloading at the site designated by Provider and pays all costs including import duties and taxes.

14. MISCELLANEOUS

14.1 **Force Majeure.** "**Force Majeure**" means and includes acts of God; strikes and labor problems affecting an industry or region generally; lightning, fire, flood, washout, storm, endemic or pandemic (or related government actions in connection with any endemic or pandemic or other actions of the elements; government actions, including embargos, sanctions, prohibitions; war, civil disturbances or other imposition of sanctions by a governmental authority with jurisdiction over a Party; and other similar circumstances or occurrences which are beyond the reasonable control of the Party that materially prevent such Party from performing any of such Party's obligations under this Agreement. Neither Party shall be liable for non-fulfilment of its obligations or in breach under this Agreement if such non-fulfilment is due to Force Majeure for the duration of such Force Majeure. Each Party shall use reasonable efforts to mitigate adverse consequences in the event of such Force Majeure. A Party that is prevented from performing any of its obligations due to Force Majeure will promptly give notice to the other Party of the event and the obligations as to which performance is prevented or delayed. If a Force Majeure situation continues for more than [***], the Parties will discuss an appropriate resolution that may include termination of a Work Order or this Agreement.

14.2 **Assignment.** This Agreement may not be assigned by a Party without the prior written consent of the other Party; provided, however, that a Party may assign this Agreement to an Affiliate with a net worth or insurance commensurate with the obligations, and sufficient capacity and personnel, to be assumed or to any company with which such assigning Party may merge or to any company to which such assigning Party may transfer its assets to which this Agreement relates. Any purported assignment in violation of this Section 14.2 is void.

14.3 **Notices.** All notices, requests, demands and other communications required under this Agreement must be in writing and will be deemed to have been given or made and sufficient in all respects when delivered by reputable international courier to the following addresses:

To Client: [***]	
To Provider: [***]	

14.4 **Independent Contractor.** The Parties are independent contractors, and nothing contained in this Agreement may be deemed or construed to create a partnership, joint venture, employment, franchise, agency, fiduciary or other relationship between the Parties.

14.5 **Non-Solicitation.** During the term of this Agreement and for [***] thereafter, Client shall not directly or indirectly induce or solicit (or authorize or assist in the taking of any such actions by any third party) any employee or consultant of Provider or any of its Affiliates to leave his or her employment or business association; provided, however, this restriction shall not apply to (i) unsolicited inquires made by an employee of a party to the other party, (ii) inquiries received from an employee of a party as the result of a general notice or advertisement placed by the other party for employees or (iii) inquiries resulting from an employment search firm utilized by an employee.

14.6 **Governing Law.** The laws of the State of New York, USA, without giving effect to principles of conflict of laws, govern all matters relating to this Agreement and the enforcement and interpretation thereof. The United Nations Convention on Contracts for the International Sale of Goods will not apply to this Agreement. This provision shall operate without prejudice to either Party's ability to seek injunctive or other interlocutory relief in any United States court accepting jurisdiction in order to protect and enforce its Intellectual Property rights.

14.7 **Arbitration.** The Parties shall engage in good faith consultation to resolve any dispute arising out of or in connection with this Agreement. Such consultation will begin immediately after one Party has delivered to the other Party a request for consultation. If the dispute cannot be resolved within [***] following the date on which the request for consultation is delivered, then either Party may submit the dispute to be finally settled by arbitration administered in accordance with the procedural rules of the International Court of Arbitration of the International Chamber of Commerce (the "ICC") in effect at the time of submission. The arbitration will be governed by the laws of the State of New York, USA. The place of arbitration will be New York. The official language of the arbitration will be English. The tribunal will consist of one arbitrator to be appointed by the ICC. The arbitration proceedings will be confidential, and the arbitrator may issue appropriate protective orders to safeguard each Party's Confidential Information. During the course of arbitration, the Parties shall continue to implement the terms of this Agreement including all Work Orders then in effect. The arbitral award will be final and binding upon the Parties, and the Party to the award may apply to a court of competent jurisdiction for enforcement of the award. Notwithstanding the foregoing, each Party has the right to institute an action in a court of proper jurisdiction in the United States for injunctive or other equitable relief pending a final decision by the arbitrator.

14.8 **Entire Agreement; Non-Reliance.** This Agreement contains the entire agreement between the Parties with respect to the subject matter of this Agreement. Prior

agreements are hereby superseded. For the avoidance of doubt, this Agreement shall supersede that certain Confidentiality Agreement, dated as of [***]; provided, however, that all "Confidential Information" disclosed or received by the Parties thereunder will be deemed "Confidential Information" hereunder and will be subject to the terms and conditions of this Agreement. Each Party disclaims that it is relying on any representations or warranties other than those set forth in this Agreement, and irrevocably waives any rights that it might otherwise have to extra-contractual remedies, including claims in tort relating to communications outside of this Agreement.

14.9 **Amendment.** No modification or waiver of any term of this Agreement or any other form of amendment to this Agreement will be binding unless made expressly in writing and signed by both Parties. An amendment to this Agreement will only be incorporated into Work Orders entered into after the date of the amendment.

14.10 **No Third Party Beneficiaries.** The provisions of this Agreement are for the sole benefit of the Parties.

14.11 **Waiver.** The waiver by either Party of any breach of any term of this Agreement will not constitute a waiver of any other breach of the same or any other term. Failure or delay on the part of either Party to fully exercise any right under this Agreement will not constitute a waiver or otherwise affect in any way the same or any other right.

14.12 **Severability.** If any provision in this Agreement is held to be invalid, illegal or unenforceable in any respect, then (a) the provision will be replaced by a valid and enforceable provision that achieves as far as possible the intention of the Parties and (b) all other provisions of this Agreement will remain in full force and effect as if the original agreement had been executed without the invalidated, illegal or unenforceable provision.

14.13 **Independent Counsel**. Each Party has had the opportunity to consult independent counsel, and as such, this Agreement will not be construed to have been drafted by one Party or the other but will be construed as having been jointly drafted when interpreting its provisions.

14.14 **Counterparts.** This Agreement may be executed in one or more counterparts, each of which will be deemed an original, but all of which together constitute one and the same instrument. Executed counterparts may be exchanged by facsimile or e-mail in PDF or similar electronic format.

[Signature page follows]

Thus, this Agreement was executed on the date stated in the introductory clause.

WuXi Biologics (Hong Kong) Limited	**Adagio Therapeutics, Inc.**
By: /s/ Zhisheng Chen Name: Zhisheng Chen Title: CEO	By: /s/ Halley Gilbert Name: Halley Gilbert Title: COO

Exhibit A—Form of Work Order

WORK ORDER (NUMBER [•])

This work order is dated [•] and is between [•] ("**Client**") and [•] ("**Provider**").

The terms of the Master Services Agreement between Adagio Therapeutics, Inc. and WuXi Biologics (Hong Kong) Limited, dated [•] (the "**Master Services Agreement**"), are hereby incorporated by reference into this Work Order. Any modifications to the Master Services Agreement will be deemed to be references to this Work Order automatically. Each capitalized term used but not defined in this Work Order has the meaning given in the Master Services Agreement.

1. SERVICES INFORMATION

1.1 **Title**

[Project title]

1.2 **Description**

[Description of the Services including deliverables and specifications]

1.3 **Tasks and Timeframe.** Provider shall complete the Services in accordance with the following schedule:

	Task	Completion Date
1		
2		
3		
4		

1.4 **Reporting and Transfer of Data and Results**

[Description of how data and results should be reported and transferred to Client, including electronic protocols for secure transmission of data and instructions for physical handling and shipping of materials if chemicals are being synthesized or other materials are to be transferred to Client]

1.5 **Additional Requirements**

[Any additional requirements such as additional obligations of the parties that do not appropriately fit into the task list and special handling of materials]

2. FEES; PAYMENT SCHEDULE

2.1 **General Terms.** Expenses, milestones, payment and default and other general terms are provided in Article 3 of the Master Services Agreement.

2.2 **Contract Price and Upfront Payment.** The Contract Price will be USD [•]. On signing of this Work Order, Client shall pay Provider [•] % of the Contract Price as a non-refundable upfront payment.

2.3 **Milestones.** The table below lists milestones and related information.

	Milestone	Deliverable	Milestone Payment
1	*[Description including work required, criteria for achievement and timeline]*	[•]	[•]
2	[•]	[•]	[•]

2.4 **Payment Instructions.** Unless an invoice provides otherwise, Client shall pay the invoice in USD by wire transfer to the account listed below (as may be amended from time to time):

Beneficiary Name	[***]				
Beneficiary Address	[***]				
Beneficiary Intermediate Bank	[***]				
Beneficiary Intermediate Bank SWIFT Address	[***]				
Beneficiary Bank Name	[***]				
Bank Address	[***]				
Branch Name	[***]	**Bank Account Number**	[***]		
Bank Code	[***]	**Branch Code**	[***]	**SWIFT Address**	[***]

3. COMMUNICATIONS

3.1 **Technical Communications.** All technical communications required under this Work Order are to be sent via reputable international courier or email and addressed as follows:

If to Client:	**If to Provider:**
[•] [•] [•] Attn: [•] Tel.: [•] Email: [•]	[•] [•] [•] Attn: [•] Tel.: [•] Email: [•]

Thus, this Work Order is executed on the date stated in the introductory clause.

Adagio Therapeutics, Inc.	**WuXi Biologics (Hong Kong) Limited**
By:_____ Name: Title:	By:_____ Name: Title:

Exhibit B—Manufacturing

15. MANUFACTURING AND COMPLIANCE

15.1 **Specifications and Manufacturing Process**. Provider shall manufacture each Product in accordance with the written specifications for the Product as agreed to by the Parties (the "**Specifications**"). Client may modify the Specifications; provided, however, that Provider's consent is required for any modification that would significantly increase costs. Provider shall negotiate in good faith with Client with the aim of agreeing on a mutually acceptable allocation of the increased costs.

15.2 **Quality Agreement.** This Agreement incorporates the quality assurance requirements of a quality agreement entered into between the Parties relating to Product, as may be amended or restated in writing from time to time by the Parties (the "**Quality Agreement**"). If there is a contradiction between a requirement of the Quality Agreement and another provision of this Agreement or a Work Order, then the requirement of the Quality Agreement will take precedence unless this Agreement or the Work Order specifically states that its provision takes precedence.

15.3 **Regulatory Assistance.** Provider shall, at Client's cost, provide Client with all supporting data and information relating to manufacturing of the Product that is reasonably necessary for obtaining and maintaining regulatory approvals relating to the manufacturing.

16. QUALITY RELEASE AND DELIVERY

16.1 **Quality Release.** Product may not be delivered to Client until a person authorized by Provider having the necessary qualifications, experience and authority to oversee quality assurance of the manufacture and determine the suitability of individual batches for release under Applicable Law has (a) conducted analyses using the analytical methods agreed to in writing by the Parties, (b) executed the Certificate of Analysis applicable to the Product and such other batch documentation that may be reasonably requested by Client and (c) completed any other certifications or documents and other activities that may be required to release the Product under Applicable Law and the Quality Agreement. Notwithstanding the foregoing, at Client's request, Provider may deliver "restricted" Product prior to delivery of the Certificate of Analysis. The request must be accompanied by Client's written acknowledgement that (i) the Product has been delivered without a Certificate of Analysis, (ii) accordingly, the Product cannot be administered to humans until transmittal of the Certificate of Analysis, and (iii) that Client nevertheless accepts full risk of loss, title and ownership of the Product. The delivery of such restricted Product will be subject to such testing requirements as Provider may reasonably require.

16.2 **Delivery.** Provider shall deliver the Product in accordance with Section 13 of this Agreement.

16.3 **Acceptance; Damage.** Client shall diligently examine the Product as soon as practicable after receipt. Client shall notify Provider (a) within [***] of receipt for claims relating to visible damage, and (b) within [***] after Provider's dispatch notice for claims relating to non-delivery. Client shall make damaged Product and packaging materials available for inspection and comply with reasonable requirements of any insurance policy covering the Product.

17. NON-CONFORMING PRODUCT

17.1 **Warranty.** Provider warrants to Client that each Product supplied will have been manufactured in accordance with, and will comply with, this Agreement, the Quality Agreement, the applicable Work Order, the Specifications and Applicable Law (the "**Warranty**").

17.2 **Non-Conformance.** Client, within [***] after receiving the shipment, shall notify Provider in writing that the Product does not conform to the Warranty and provides supporting documentation with respect thereto. A shipment that is not rejected pursuant to the preceding sentence will be deemed accepted by Client; provided, that, in the case of a latent defect such [***] period shall not apply and Client shall advise Provider promptly after identifying any such latent defect. The Provider shall not be responsible for latent defects identified by Client after [***] of Client's receipt of Product.

17.3 **Disputes.** If the Parties are unable to agree as to whether a Product conforms to the Warranty, Client shall send a sample of the Product for testing to an independent quality control laboratory mutually chosen by and agreed upon by the Parties. The findings of the laboratory will be binding on the Parties. The cost of inspections and testing by the laboratory will be borne equally by each Party.

17.4 **Manufacturing Failure/Product Non-Conformance.** If Provider is unable to manufacture Product per the Warranty after a non-GMP or GMP manufacturing run has been initiated on the Product, or determines, prior to delivery to Client, that Product does not conform to the Warranty ("**Failure**"), an analysis of root cause will be required.

(i) If the Failure of either the Drug Substance or Drug Product is due to Client Materials, Client's inherent process, or due to compliance to any written instructions provided by Client, Client will be liable for paying for such non-conforming Product. If Client requests Provider to replace such non-conforming Product, Provider shall replace such non-conforming Product as soon as is reasonably possible and Client will pay the price for Services and all pass-through and raw material costs associated with providing the replacement Product. Client will be also responsible for collecting or disposing of the non-conforming Product, at its own expense.

(ii) If the Failure applies to Drug Substance and is not due to Client Materials, Client's inherent process, or due to compliance to any instructions provided by Client, then, at Client's option, Provider shall either (A) promptly replace such non-conforming Drug Substance as soon as reasonably possible, and Provider shall bear the cost for services to manufacture the Drug Substance to replace such non-conforming Drug Substance and Client shall pay for the raw material and pass-through costs associated with providing the replacement Drug Substance, or (B) if Provider cannot complete such replacement, Provider shall refund the service fee within [***] after such attempt.

(iii) If the Failure applies to Drug Product and is not due to Client Materials, Client's inherent process, or due to compliance to any written instructions provided by Client, Client may, at customer's sole discretion, elect for Provider to replace or refund such non-conforming Drug Product. If Client requests Provider to replace the non-conforming Drug Product under these circumstances, Client shall provide sufficient Drug Substance for the Drug Product batch. If the Drug Substance needs to be manufactured, Client shall pay the price for services to manufacture the Drug Substance and all raw material and pass-through costs associated with Drug Substance manufacture. Client shall pay the raw material and pass-through costs for all batches of the Drug Product production required to replace the non-conforming Drug Product. Provider shall provide a free slot for GMP Drug Product manufacturing to replace such non-conforming Drug Product as soon as reasonably possible.

(iv) Notwithstanding the foregoing clauses (ii) and (iii), if the Failure is due to circumstances outside of Provider' control, including but not limited to Force Majeure, third party bag or container leak or failure, where an insurance claim can cover all or part of the loss of Product, Client may elect for Provider to refund the amount covered by insurance after deduction of Provider's cost within [***] of the insurance claim being paid out to Provider and if Client requests Provider to replace the non-conforming Product, Provider will replace such non-conforming Product as soon as reasonably possible and Client will pay the price for Services for any Product manufacture and all raw material and pass-through costs associated with the manufacture of the new Products delivered by Provider in replacement of such non-conforming Products.

Exhibit 10.20

MASTER SERVICES AGREEMENT

THIS MASTER SERVICES AGREEMENT (this **"Agreement"**) is made as of November 15, 2022 (the **"Effective Date"**) by and between **Invivyd, Inc.**, a Delaware corporation with a principal office at 1601 Trapelo Road, Suite 178, Waltham, MA 02451 (**"Invivyd"**), and Population Health Partners, L.P., a Delaware limited partnership, with a principal office at 1200 Morris Turnpike, Suite 3005, Short Hills, NJ 07078 (**"PHP"**).

Invivyd and PHP desire that PHP provide Invivyd with certain services (the **"Services"**) and create certain deliverables (the **"Deliverables"**) from time to time in accordance with the terms of this Agreement. In consideration of the agreements and mutual covenants contained in this Agreement and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Invivyd and PHP agree as set forth herein.

1. Work Orders. Any Services or Deliverables will be set forth in one or more work orders (**"Work Order"**). Work Orders shall be in writing, signed by both parties and, at a minimum, identify and adequately describe the Services and/or Deliverables and state the applicable fees and compensation to be paid to PHP. Either party may request a change to a Work Order, and, upon such request, the parties will negotiate the requested change diligently and in good faith. Any amendment to a Work Order must be agreed upon in writing prior to the commencement of the changes. Notwithstanding anything to the contrary in any Work Order, this Agreement shall govern all Work Orders, and to the extent there is any conflict, discrepancy or inconsistency between a Work Order and the terms of this Agreement, the terms of this Agreement shall control, unless the Work Order specifically references the conflict, discrepancy or inconsistency and provides that it shall govern.

2. Performance.

2.1 Provision of Services. PHP shall use commercially reasonable efforts to perform the Services in a professional, diligent, timely and workmanlike manner and in accordance with this Agreement and any applicable Work Order(s). As reasonably requested by Invivyd, PHP will provide Invivyd with progress reports and other information related to the Services and/or Deliverables. Each party may designate a "Project Leader" to be the contact person for communications regarding the Services provided under that Work Order. Any Services performed on behalf of Invivyd must be in compliance with Invivyd's Code of Business Conduct and Ethics and applicable policies and procedures, including but not limited to clinical and regulatory policies and procedures, all of which shall be provided in advance and in writing to PHP.

2.2 Promotional Materials. If the Services and/or Deliverables involve any Invivyd promotional materials, such materials shall be subject to Invivyd's internal review and approval processes. PHP shall not disseminate any promotional materials without Invivyd's prior written consent.

2.3 On Site Security Procedures. To the extent PHP performs any of the Services on Invivyd premises, PHP shall use commercially reasonable efforts to comply with Invivyd's security procedures, which shall be provided to PHP in writing in advance of such performance.

2.4 Subcontracting. PHP may not, in whole or in part, subcontract or delegate the performance of any Services without Invivyd's prior written consent. **"Permitted Subcontractor"** means a third

party to whom the performance of such Service has been subcontracted or delegated with Invivyd's prior written consent. PHP shall remain liable for any Services subcontracted or delegated to any third party in accordance with this Agreement to the same extent as if such Services had not been subcontracted.

2.5 **Affiliates. "Affiliate"** means, with respect to each party to this Agreement, any corporation, company, partnership, joint venture and/or firm which controls, is controlled by or is under common control with that party. As used in this Section 2.5, **"control"** means (i) in the case of corporate entities, direct or indirect ownership of at least fifty percent (50%) of the stock or shares having the right to vote for the election of directors (or such lesser percentage that is the maximum allowed to be owned by a foreign corporation in a particular jurisdiction), and (ii) in the case of non-corporate entities, the direct or indirect power to manage, direct or cause the direction of the management and policies of the non-corporate entity or the power to elect at least fifty percent (50%) of the members of the governing body of such non-corporate entity.

2.6 **Representatives. "Representatives"** means, with respect to each party to this Agreement, its directors, officers, employees, agents, contractors and consultants.

3. Representations and Warranties by Invivyd and PHP.

3.1 Each of Invivyd and PHP represents and warrants that:

3.1.1 It has the full power and authority to enter into and perform this Agreement, and this Agreement is a valid and binding obligation, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

3.1.2 There are no actions pending or, to its knowledge, threatened against it or its Affiliates that are reasonably expected to materially impair its ability to perform its obligations hereunder, and it will not intentionally enter into any agreement which would reasonably be expected to materially impair its ability to perform its obligations hereunder.

3.1.3 Its execution and performance of this Agreement does not conflict with, violate or constitute a default under any of its other agreements or obligations, and it will not intentionally enter into any agreement, either written or oral, that would reasonably be expected to conflict with PHP's obligations under this Agreement or any Work Order.

3.1.4 It will comply with all applicable federal, state and local laws, regulations, professional standards, and industry codes, ordinances and orders, as amended from time to time, including but not limited to (i) the Foreign Corrupt Practices Act of 1977, (ii) the federal anti-kickback statute (42 U.S.C. §1320a-7b(b)), and state anti-kickback and other laws restricting gifts to, relationships with and information from prescribers, (iii) the federal Food and Drug Administration laws, regulations and guidance, including the federal Food, Drug and Cosmetic Act and the Prescription Drug Marketing Act, (iv) those governing the purchase and sale of securities while in possession of material, non-public information about a company, (v) state and federal privacy and data security laws, including but not limited to the federal Health Insurance Portability and Accountability Act of 1996 (**"HIPAA"**), the Health Information Technology for Economic and Clinical Health Act (**"HITECH"**), Chapter 93H of The Massachusetts General Laws and its implementing

regulations, 201 CMR 17.00, and the California Consumer Privacy Act, as amended (**"CCPA"**), Cal. Civ. Code § 1798.100, et. seq. During the Term (as defined in Section 8.1), each party shall promptly notify the other in writing of any known or expected violations of this Section 3.1.4. In addition, PHP will use commercially reasonable efforts to materially comply with all reasonable and applicable Invivyd policies and procedures as provided in writing in advance to PHP.

3.1.5 It, its Affiliates, Representatives, any Permitted Subcontractors and any other person used by PHP to perform the Services for Invivyd (a) has not been debarred, convicted, and is not subject to any pending debarment or conviction, pursuant to section 306 of the United States Food Drug and Cosmetic Act, 21 U.S.C. § 335a, (b) has not been listed by any government or regulatory agencies as (i) ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. 1320a-7b(f)) or excluded, debarred, suspended or otherwise made ineligible to participate in any such programs, or (ii) disqualified or restricted, from receiving investigational products pursuant to the government or regulatory agency's regulations, or (c) has not been convicted of a criminal offense related to the provision of healthcare items or services, and is not, to its knowledge, the subject of any such pending action, suit, claim, investigation or proceeding. Each party will promptly inform the other in writing if PHP or any person who is performing Services has been or becomes, to its knowledge, subject to any of the foregoing, or if, to its knowledge, any action, suit, claim, investigation, or proceeding relating to the foregoing is pending or threatened.

3.2 No Infringement.

3.2.1 PHP represents and warrants that the provision of Services under this Agreement will not, to its knowledge, infringe or violate any patent, copyright, trade secret or other proprietary or intellectual property right of any third party; provided, however, that PHP makes no representations or warranties regarding its use of the Materials or Invivyd Intellectual Property (each, as defined below) as contemplated under this Agreement. In addition, PHP represents and warrants that all Deliverables (excluding any Materials or Invivyd Intellectual Property included or incorporated therein) shall, to its knowledge, be delivered free of any claim of infringement of any patent, trade secret, copyright, trademark or any other proprietary or intellectual right of any person. If any Deliverable is determined to be infringing, or in Invivyd's good faith opinion is likely to be subject of a valid claim of infringement, in each case, other than as a result of the incorporation of any Materials or Invivyd Intellectual Property as contemplated hereunder or requirements or criteria set forth by Invivyd with respect to such Deliverables, PHP shall at its expense and option either (i) procure the right for Invivyd to continue using it, (ii) replace it with a non-infringing equivalent, (iii) modify it to make it non-infringing, or (iv) direct the return of the Deliverable and, if applicable, refund to Invivyd the fees paid for such Deliverable less a reasonable amount for Invivyd's use of the Deliverable up to the time of return.

3.2.2 Invivyd represents and warrants that none of the Materials or Invivyd Intellectual Property (nor any use thereof by PHP as contemplated in this Agreement) will, to its knowledge, infringe or violate any patent, copyright, trade secret or other proprietary or intellectual property right of any third party.

3.3 CCPA. If PHP accesses, collects, creates, processes or discloses any Personal Information (as that term is defined in Section 1798.140 of the California Civil Code) of any California Consumer

(as that term is defined in Section 1798.140 of the California Civil Code) ("**Consumer**") while rendering Services to Invivyd, PHP shall hold all such Personal Information in confidence in accordance with the terms of this Agreement. PHP further agrees to promptly delete and procure the deletion of all copies of such Personal Information relating to Consumers within ten (10) days after its receipt of a written request from Invivyd directing PHP to delete such Personal Information. PHP shall provide Invivyd with a certification confirming the deletion of that Personal Information, such certification to be in a form mutually agreed to by the parties. PHP further agrees to provide commercially reasonable assistance to enable Invivyd to respond to and comply with any verifiable Consumer requests concerning such Personal Information pursuant to the CCPA. PHP shall use commercially reasonable efforts to provide Invivyd with CCPA-related information within ten (10) days after its receipt from Invivyd of such request.

4. Compensation.

4.1 Invoice; Payment Terms. As full consideration for the Services rendered under a Work Order, Invivyd will pay PHP the fees or otherwise compensate PHP as set forth in the relevant Work Order. Unless otherwise specified in the Work Order, payments will be made by Invivyd within forty-five (45) days from Invivyd's receipt of invoice from PHP. To be valid, invoices must be in writing, include the applicable Invivyd purchase order number (if previously provided to PHP in writing), contain such detail as Invivyd may reasonably require, be submitted and payable in U.S. Dollars to AP@Invivyd.com. Prior to Invivyd's initial payment of fees or other compensation, PHP shall provide to Invivyd (by e-mail to AP@Invivyd.com) a completed and signed U.S. Internal Revenue Service Form W-9, *Request for Tax Payer Identification Number and Certification*, or other applicable tax withholding form.

4.2 Expenses. Invivyd will reimburse PHP for actual reasonable, appropriate and documented business expenses in accordance with the terms of the applicable Work Order; provided, however, that Invivyd will have no obligation to reimburse expenses that are (a) not approved in advance and in writing or (b) submitted to Invivyd more than ninety (90) days from the date PHP receives an invoice for such expense.

4.3 Nonconforming Work. Invivyd will have the right to reject, and shall have no obligation to pay for, any Services or Deliverables that do not meet the requirements or quality criteria set forth in this Agreement or the applicable Work Order, by delivery of a written notice to PHP, containing a reasonably detailed description of any purported failure to meet such requirements or criteria (such Service, work or Deliverable, **"Nonconforming Work"**). If reasonably practicable under the circumstances, PHP will, upon Invivyd's request and at PHP's sole expense, use commercially reasonable efforts to cure any deficiency in the Nonconforming Work in order to make such Nonconforming Work meet the applicable requirements and/or criteria. If such deficiencies are not or cannot be cured within a reasonable amount of time agreed to by the parties, PHP will refund to Invivyd all amounts paid by Invivyd to PHP in connection with the Nonconforming Work.

4.4 Taxes. Invivyd will make all payments to PHP under any Work Order without deduction or withholding for taxes including income tax withholding, Value Added Tax (**"VAT"**), duties, sales tax or a similar tax except to the extent any such deduction or withholding is required by the tax laws of any federal, state, provincial or foreign government. In the event a deduction or withholding for taxes is applicable, Invivyd will submit such deduction or withholding for taxes to the appropriate governmental authority and will provide a tax certificate to PHP. In the event

VAT or sales tax applies to the Services provided, PHP will invoice such tax to Invivyd as a reimbursable expense and, following receipt of payment, PHP will remit such tax to the relevant government authority.

4.5 Fair Market Value. The parties agree that the amount of compensation payable under any Work Order reflects the fair market value of the Services and is consistent with arm's length transactions for services of the kind as the Services. The parties agree that the selection of PHP and any payments under this Agreement and any Work Order are not, in any way, an inducement to, or in exchange for acting or agreeing (whether express or implied) to act, prescribe or cause to be prescribed, purchase, use or recommend any product of Invivyd.

4.6 Disclosure of Certain Payments. At such times and intervals as Invivyd may reasonably require, PHP shall provide Invivyd with timely reports (and supporting documentation, if requested) of any payments made to health care providers, including, but not limited to, physicians, nurses, hospitals, pharmacies and health plans, in connection with PHP's performance of the Services hereunder to allow Invivyd to meet applicable federal and/or state law reporting requirements. Reportable payments shall include, but are not limited to, fees or honoraria paid for services, meals provided and reimbursed travel, lodging and meals expenses. PHP consents to Invivyd's disclosure of such fees and expenses from time to time, if and when required by law or government regulation thereunder, without any further notification to PHP.

4.7 Financial Records; Audits. PHP shall keep true, complete and accurate records, receipts and other supporting data as Invivyd may reasonably require to verify the amounts invoiced to, and paid by, Invivyd under this Agreement and any Work Order. Such records will be available for audit by Invivyd and/or an independent accounting firm appointed by Invivyd for a period of three (3) years after the date on which the applicable Services have been completed. Such audits shall be made no more than once each calendar year during ordinary business hours and upon reasonable prior notice; provided, however, that an audit for cause may be conducted more frequently. To the extent that such audit reveals any overpayments or underpayments by Invivyd, Invivyd shall make up the amount of shortfall or, if applicable, PHP shall refund the amount of overpayment made by Invivyd, within thirty (30) days from the receipt of the audit results; provided, however, that prior to the payment of any such refund, PHP shall be entitled to have a review of such audit results conducted by independent accounting firm mutually acceptable by PHP and Invivyd, and any refund payment shall be made based solely on the determination of such independent accounting firm, which determination shall be final. PHP shall provide reasonable assistance, including making available members of its staff upon reasonable notice and during normal business hours, to facilitate such audits.

5. Proprietary Rights.

5.1 Materials. All documentation, information, data, and other materials controlled by Invivyd and furnished to PHP by or on behalf of Invivyd (the **"Materials"**) and all associated intellectual property rights (collectively, the "**Invivyd Intellectual Property**") will remain the exclusive property and Confidential Information (as defined in Section 6.1) of Invivyd. PHP will use Materials provided by Invivyd only as necessary to perform the Services and will treat the Materials in accordance with the requirements of this Section 5.1. PHP agrees that it will not use or evaluate such Materials or any portions thereof for any other purpose except as directed or permitted in writing by Invivyd. Without Invivyd's prior express written consent, PHP agrees that it will not transfer or make the Materials available to third parties.

5.2 **Inventions.** PHP assigns and agrees to assign to Invivyd all rights in the United States and throughout the world to inventions, discoveries, improvements, ideas, designs, processes, techniques, formulations, strategies, products, substances, computer programs, works of authorship, databases, mask works, trade secrets, know-how, information, data, documentation, reports, research and other creations arising or derived from or made by PHP in the performance of the Services, creation of the Deliverables or the use of Invivyd's Confidential Information (whether or not patentable or subject to copyright or trade secret protection) under this Agreement, but in each case, excluding PHP Property (collectively, the "**Inventions**"). Invivyd shall exclusively own all Inventions and all right, title and interest therein shall be exclusively vested in Invivyd. Inventions shall constitute Confidential Information of Invivyd and shall be protected by PHP in accordance with Section 6 below. For purposes of the copyright laws of the United States, Inventions will constitute "works made for hire" as defined under the United States Copyright Act, 17 U.S.C. 101, except to the extent such Inventions cannot by law be "works made for hire," in which case, PHP irrevocably assigns all copyrights in the Inventions, including the right to prepare derivative works, to Invivyd. PHP represents and warrants to Invivyd that all PHP Representatives involved in providing Services or creating Deliverables have entered into or will be directed to enter into prior to commencing the Services, a written agreement which assigns to PHP all Inventions created by such PHP Representatives during the course of his or her employment by, or other provision of services to, PHP.

5.3 **Cooperation.** During and after the Term of this Agreement, PHP will use commercially reasonable efforts, and will direct its Affiliates, Representatives and any Permitted Subcontractors performing Services under a Work Order to use commercially reasonable efforts, to cooperate reasonably in obtaining patent and other proprietary protection for any patentable Deliverables, all in the name of Invivyd and at Invivyd's sole cost and expense. Such cooperation may include, without limitation, executing and delivering all requested applications, assignments and other documents, and taking such other reasonable measures as Invivyd may reasonably request in order to perfect and enforce Invivyd's rights in the Deliverables. PHP irrevocably designates and appoints Invivyd its agent and attorney-in-fact to execute, file and deliver any such documents and do all other lawfully permitted acts on behalf of PHP, its Affiliates and Representatives if, within a reasonable period of time under the circumstances following written notice from Invivyd, PHP, its Affiliates or Representatives fail to do so to Invivyd's reasonable satisfaction in accordance with the terms hereof.

5.4 **PHP Property.** Notwithstanding the foregoing, PHP will retain full ownership rights in and to all inventions, discoveries, ideas, designs, processes, techniques, formulations, strategies, products, substances, computer programs, works of authorship, databases, mask works, know-how, trade secrets, improvements, information, data, documentation, reports, research and other creations or materials developed by or on behalf of, or obtained or owned by, PHP or its Affiliates or Representatives (collectively, the "**PHP Property**") prior to or independent of the performance of the Services or any Work Order and without use of Invivyd's Confidential Information, regardless of whether such PHP Property is used in connection with PHP's performance of the Services or creation of the Deliverables. To the extent any PHP Property is used in connection with PHP's performance of the Services or creation of the Deliverables, PHP hereby grants to Invivyd a perpetual, non-exclusive, fully paid-up, royalty-free, irrevocable worldwide license, with the right to grant sublicenses, to use such PHP Property solely to the extent required for Invivyd's use of the Deliverables.

5.5 Work at Third Party Facilities. PHP will not transfer Materials to any third party, use any third-party facilities, in performing the Services or incorporate any third party intellectual property into any Deliverables, in each case, without Invivyd's prior written consent.

5.6 Records. PHP will maintain all materials and all other data and documentation obtained or generated by PHP in the course of preparing for and providing Services hereunder, including all computerized records and files (the **"Records"**) in a secure area reasonably protected from fire, theft and destruction. These Records will be "works made for hire" and will remain the exclusive property of Invivyd. Promptly following written instruction of Invivyd, all Records will, at PHP's option either be (a) delivered to Invivyd or to its designee in such form as is then currently in the possession of PHP, or (b) disposed of, at the direction and written request of Invivyd, unless such Records are otherwise required to be stored or maintained by PHP as a matter of law or regulation and excluding any archival copies retained in accordance with its normal procedures. PHP may, however, retain copies of any Records as are reasonably necessary for regulatory or insurance purposes, subject to PHP's obligation of confidentiality**.**

6. Confidential Information.

6.1. Definition. For purposes of this Agreement, the term "**Confidential Information**" shall mean any and all non-public, proprietary or confidential information of a party hereto (the "**Disclosing Party**") disclosed to the other party hereto (the "**Recipient**"), before, on or after the Effective Date and furnished in any form, including written, oral, visual, or electronic form and/or in any other media or manner, whether or not labeled "Confidential". Confidential Information includes but is not limited to (a) all proprietary technologies, know-how, trade secrets, discoveries, inventions and any other intellectual property (whether or not patented), (b) scientific data and sequence information, development and marketing plans, regulatory and business strategies, financial information, forecasts, personnel information and customer lists, (c) all information of third parties that Disclosing Party has an obligation to keep confidential, (d) other materials prepared by either party, containing or based in whole or in part on any such Confidential Information and (e) the terms, conditions and existence of this Agreement. For the avoidance of doubt and as provided for herein, the Deliverables and Materials constitute the Confidential Information of Invivyd only.

6.2. Obligations. The Recipient will use any Confidential Information of Disclosing Party solely to perform the Services or exercise its rights or perform its obligations under this Agreement or a Work Order and will treat Disclosing Party's Confidential Information with the same degree of care it uses to protect its own Confidential Information, but in no event with less than a reasonable degree of care. During the Term and for a period of five (5) years thereafter, Recipient will not directly or indirectly publish, disseminate or otherwise disclose, use for its own benefit or for the benefit of a third party, deliver or make available to any third party, any of Disclosing Party's Confidential Information other than in furtherance of the purposes of this Agreement and only with the prior written consent of Disclosing Party. Recipient will exercise all reasonable precautions to physically protect the integrity and confidentiality of the Disclosing Party's Confidential Information. Recipient may disclose Disclosing Party's Confidential Information to its Representatives, but only to the extent necessary to perform the Services. Recipient agrees that any such Representatives to whom Disclosing Party's Confidential Information is disclosed shall be advised of Recipient's obligations under this Agreement and shall be bound by the terms at least as restrictive as the terms hereof to protect the confidentiality of Disclosing Party's Confidential Information pursuant to (x) a written agreement with Recipient, or (y) the rules and standards of professional conduct to which such Representative is bound.

6.3. **Exceptions.** Notwithstanding the foregoing, Recipient will have no obligations of confidentiality and non-use with respect to any portion of Disclosing Party's Confidential Information that:

(a) is or later becomes generally available to the public by use, publication or the like, through no violation of this Agreement on the part of Recipient, its Affiliates or its Representatives;

(b) is disclosed without restriction to Recipient, its Affiliates or Representatives by a third party who is in legal possession of such information and whose disclosure to Recipient, its Affiliate or Representative does not, to the knowledge of Recipient, violate any contractual, legal or fiduciary obligation to Disclosing Party or any third party;

(c) is lawfully in Recipient's possession (by means other than prior disclosure from Disclosing Party) without any obligation to maintain confidentiality at the time of its receipt hereunder; or

(d) is independently developed by Recipient without aid, use or benefit of Confidential Information.

In the event that Recipient is required by law or court order to disclose any Confidential Information, Recipient will, to the extent permissible, give Disclosing Party prompt notice thereof so that Disclosing Party may, at its sole cost and expense, seek an appropriate protective order to obtain confidential treatment for such disclosed information. In addition, Recipient will, at Disclosing Party's sole cost and expense, (i) take all reasonable actions to obtain confidential treatment for any disclosed Confidential Information; (ii) reasonably cooperate with Disclosing Party in its efforts to seek such a protective order; and (iii) limit such disclosure of Disclosing Party's Confidential Information to the fullest extent permitted under applicable law based on the advice of counsel.

6.4. S**ecurities Laws**. United States securities laws prohibit any person who is given access to material, non-public information concerning a publicly traded company from purchasing or selling securities in that company or from communicating the information to any other person who is likely to purchase or sell securities of that company. In connection with this Agreement, PHP may have access to information that is considered material, non-public information and PHP agrees not to use, or cause any other person to use, such information to purchase or sell securities in any publicly traded company.

7. Indemnification.

7.1 **Indemnification by PHP.** Subject to Section 7.3, PHP will defend, indemnify and hold harmless Invivyd, its Affiliates and each of their respective directors, officers, employees, agents, licensors, successors and assigns (collectively, the **"Invivyd Indemnitees"**) from any loss, liability or expense incurred in connection with a claim, demand, action, suit or proceeding brought by a third party (a **"Claim"**), to the extent arising from or related to (a) PHP's breach of any of its obligations, representations or warranties under this Agreement or (b) the infringement or alleged infringement of any third party proprietary or intellectual property rights to the extent arising from Invivyd's use of PHP Property as permitted under the license granted to Invivyd in Section 5.4.

7.2 Indemnification by Invivyd. Subject to Section 7.3, Invivyd will defend, indemnify and hold harmless PHP, its Affiliates and each of their respective directors, officers, employees, agents, licensors, successors and assigns (collectively, the **"PHP Indemnitees"**) from any loss, liability or expense incurred in connection with a Claim, to the extent arising from or related to (a) Invivyd's breach of any of its obligations, representations or warranties under this Agreement, (b) any materials PHP prepares or publishes for Invivyd to the extent that such materials are (i) based upon information provided by Invivyd to PHP prior to their preparation or publication or (ii) are prepared according to the requirements and criteria of Inviyd, or (c) the infringement or alleged infringement of any third party proprietary or intellectual property rights to the extent relating to PHP's use of the Materials or any Invivyd Intellectual Property as contemplated under this Agreement

7.3 Indemnification Procedures. The party seeking to be indemnified (the **"Indemnified Party"**) will provide prompt written notice of a Claim or events likely to give rise to a Claim to the party with the obligation to indemnify (the **"Indemnifying Party"**) (in any event within sufficient time so as not to prejudice the defense of such Claim). The Indemnifying Party shall be given the opportunity at all times to control the defense of the Claim, with the cooperation and assistance of the Indemnified Party; provided, however, that the Indemnifying Party shall not settle any Claim with an admission of liability or wrongdoing by the Indemnified Party without such party's prior written consent.

7.4 Limitation on Liability. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES (INCLUDING, BUT NOT LIMITED TO, BUSINESS INTERUPTION, LOST PROFITS AND LOST BUSINESS) ARISING OUT OF THIS AGREEMENT OR ANY WORK ORDER, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY. THIS LIMITATION WILL APPLY EVEN IF THE OTHER PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGE; PROVIDED, HOWEVER, THAT THIS LIMITATION WILL NOT APPLY TO DAMAGES RESULTING FROM (A) BREACHES BY A PARTY OF ITS DUTY OF CONFIDENTIALITY AND NON-USE IMPOSED UNDER SECTION 6, (B) A PARTY'S INDEMNIFICATION OBLIGATIONS TO THE EXTENT A THIRD PARTY RECEIVES A JUDGMENT AWARDING SUCH SPECIAL INCIDENTAL, CONSEQUENTIAL, INDIRECT OR PUNITIVE DAMAGES, OR (C) A PARTY'S GROSS NEGLIGENCE, WILLFUL MISCONDUCT OR FRAUD. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, IN NO EVENT WILL EITHER PARTY BE LIABLE FOR ANY AMOUNT IN EXCESS OF SEVEN TIMES (7X) THE AMOUNT OF FEES ACTUALLY PAID TO PHP PURSUANT TO THIS AGREEMENT OR ANY WORK ORDER; PROVIDED THAT THE LIMITATION IN THIS SENTENCE SHALL NOT APPLY TO DAMAGES ARISING OUT OF OR RESULTING FROM THE CIRCUMSTANCES SET FORTH IN CLAUSES (A), (B) OR (C) OF THE PREVIOUS SENTENCE.

7.5 Insurance. Each party will carry, with financially sound and reputable insurers, sufficient and customary insurance coverage (including, but not limited to, comprehensive general liability and workers' compensation) to secure the performance of its obligations under this Agreement and upon request, each party will provide certificates of insurance evidencing such coverage.

8. Term and Termination.

8.1 Term. This Agreement will commence on the Effective Date and continue for one (1) year, (the **"Initial Term"**) unless earlier terminated in accordance with this Section 8. This Agreement shall automatically renew for subsequent periods of one (1) year each (each a **"Renewal Term,"** and together with the Initial Term, the **"Term"**) unless either party notifies the other at least thirty (30) days prior to the expiration of the then current Initial Term or Renewal Term, as applicable, of its intent not to renew. Any Work Order shall commence on its respective effective date and shall terminate upon the completion of Services and delivery of Deliverables to be provided thereunder or as otherwise set forth in such Work Order, unless earlier terminated in accordance with this Section 8. Notwithstanding the foregoing, if any Work Order has been entered into prior to this Agreement's expiration and remains in effect at what would otherwise be this Agreement's expiration, then this Agreement shall not expire and shall continue in full force and effect until PHP's completion of any unperformed obligations under any such Work Order. During the Term and for a period of one (1) year thereafter, PHP and its Affiliates shall not, without Invivyd's prior written consent, perform any Services for any third party that develops or commercializes products directly in competition with any Invivyd product that is related to a Work Order or Services performed thereunder.

8.2 Termination by Either Party for Breach or Bankruptcy. Either party may terminate this Agreement or any Work Order immediately if: (a) the other party materially breaches the terms of this Agreement or any Work Order and such breaching party fails to cure the breach within thirty (30) days after receipt of written notice from the non-breaching party specifying the breach; (b) the other party materially breaches the terms of this Agreement or any Work Order and such material breach cannot be cured (for example, breach of confidentiality obligations); or (c) the other party shall have become bankrupt or made an assignment for the benefit of its creditors, or there shall have been appointed a trustee for all or substantially all of such party's property, or any case or proceeding shall have been commenced or other action taken by or against such party in bankruptcy or seeking reorganization, liquidation, dissolution, winding up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency or reorganization or other similar act of law of any jurisdiction now or hereafter in effect; provided, however, that in case of an involuntary case or proceeding, such proceeding is not dismissed within sixty (60) days of its official commencement.

8.3 Termination by Invivyd. Invivyd may terminate this Agreement or any Work Order (a) at any time and for any reason upon thirty (30) days' prior written notice to PHP, or (b) immediately, if at any time, PHP breaches the representation and warranty set forth in Section 3.1.5 or otherwise becomes subject to any of the actions, suits, claims, investigations, or proceedings set forth in Section 3.1.5.

8.4 Effect of Termination or Expiration. Unless otherwise specified under the terms of a Work Order, upon termination or expiration of this Agreement, neither PHP nor Invivyd will have any further obligations under this Agreement, or in the case of termination or expiration of a Work Order, under that Work Order, except that:

(a) In the case of a termination, PHP will cease all Services in progress in an orderly manner as soon as practical and use commercially reasonable efforts to cancel or otherwise limit any related costs or expenses (including any obligations to third parties); provided, however, that if Invivyd provides specific wind-down instructions or instructions that Services in

progress should be completed, then this Agreement and the applicable Work Order shall not terminate until such Services are completed;

(b) Promptly following Invivyd's written request, PHP will deliver to Invivyd or, at Invivyd's option, dispose of, any Materials in its possession or control and all Deliverables developed through termination or expiration;

(c) No later than sixty (60) days after the date of termination or the completed performance of any wind-down instructions from Invivyd, PHP shall provide Invivyd with a final reconciliation containing an itemized accounting of Services performed, expenses incurred and payments received to determine any and all amounts owed to or by each party. Invivyd will pay PHP all unpaid (and undisputed, to the extent such Work Order contains provisions relating to fee disputes) fees for Services performed and all permitted reimbursable expenses through the termination date in accordance with the provisions of this Agreement and any applicable Work Order(s). In addition, Invivyd will reimburse PHP for all reasonable, non-cancellable obligations to third parties incurred by PHP in the course of its performance of Services and any reasonable costs incurred in connection with performing Invivyd's wind-down instructions, in each case in accordance with the provisions of this Agreement. PHP will promptly refund any monies paid in advance by Invivyd for Services not rendered and in excess of any applicable payments owed by Invivyd under this Agreement or any applicable Work Order(s). Any net amount owed by either party will be paid within sixty (60) days following receipt of the itemized accounting; and

(d) Promptly following Disclosing Party's written request, Recipient will return to Disclosing Party and/or destroy, at Recipient's option, all Confidential Information and all tangible items to the extent containing such Confidential Information, and all copies thereof in the possession or control of Recipient, Recipient's Affiliates, Representatives or any Permitted Subcontractors, provided to Recipient under this Agreement or under any Work Order which has been terminated or has expired; provided, however, that Recipient may retain one (1) copy in the separate files of Recipient's legal counsel solely for legal compliance purposes and with respect to electronic copies, Recipient shall (i) be obligated to use only commercially reasonable efforts to remove all active copies and (ii) not be obligated to delete archival copies retained in accordance with its normal procedures, or to remove any hidden or partial copies; provided further, however, that notwithstanding anything to contrary herein, all retained Confidential Information shall continue to be subject to the confidentiality and non-use obligations set forth herein. Upon Disclosing Party's request, an authorized representative of Recipient shall certify to Recipient's compliance with this Section 8.4(d).

9. Miscellaneous.

9.1 Public Statements; Use of Name. Except to the extent required by applicable law, regulation or court order or the rules of the U.S. Securities and Exchange Commission, any stock exchange or NASDAQ, neither party will make any public statements or releases concerning this Agreement or the transactions contemplated by this Agreement or use the other party's name in any form of advertising, promotion or publicity, or otherwise, in each case, without obtaining the prior written consent of the other party. Notwithstanding anything to the contrary in the foregoing, each party consents to the other party's public disclosure of the existence of this Agreement and the fact that PHP is providing Services to Invivyd.

9.2 Non-solicitation. During the Term and for a period of one (1) year thereafter:

(a) PHP shall not (i) solicit any person, who is employed at the senior management-level by Invivyd and with whom PHP had contact in the performance of the Services, to terminate such person's employment by Invivyd or (ii) hire such employee; and

(b) Invivyd shall not (i) solicit any person, who is employed at the senior management-level by PHP and with whom Invivyd had contact in the performance of the Services, to terminate such person's employment by PHP or (ii) hire such employee.

As used herein, the term "solicit" shall (a) include, without limitation, requesting, knowingly encouraging, assisting or causing, directly or indirectly any such employee to terminate such person's employment by Invivyd (in the case of PHP) or PHP (in the case of Invivyd), and (b) exclude any general solicitation through public advertisements or media, or recruitment efforts conducted by an employment agency. This Section 9.2 shall not apply to any employee who (x) approaches PHP on an unsolicited basis following the cessation of such person's employment by Invivyd, or (y) approaches Invivyd on an unsolicited basis following the cessation of such person's employment by PHP.

9.3 Remedies. It is understood and agreed that the parties may be irreparably injured by a breach of this Agreement; that money damages would not be an adequate remedy for any such breach; and that the parties will be entitled to seek equitable relief, including injunctive relief and specific performance, without having to post a bond, as a remedy for any such breach, and such remedy will not be the exclusive remedy for any breach of this Agreement.

9.4 Governing Law. This Agreement will be governed by, construed, and interpreted in accordance with the laws of the Commonwealth of Massachusetts, U.S.A., without reference to principles of conflicts of laws. The parties further agree that the venue of any action, injunctive application or dispute determinable by a court of law arising out of this Agreement or any Work Order shall be the Commonwealth of Massachusetts, and that the federal and state courts therein shall have jurisdiction over the subject matter and the parties.

9.5 Independent Contractors. The parties are independent contractors, and nothing contained in this Agreement is intended, and shall not be construed, to (a) constitute the parties as partners, principal and agent, employer and employee, joint venturers or co-owners, or (b) entitle or allow either Party to create or assume any obligation on behalf of the other Party for any purpose whatsoever, including but not limited to, making any representation, contract or commitment on behalf of the other Party.

9.6 Assignment. Neither this Agreement nor any Work Order may be transferred or assigned, in whole or in part, by either party without the prior written consent of the other party. However, Invivyd may transfer or assign this Agreement and any Work Orders, in whole or in part, without the prior written consent of PHP, in connection with a merger, consolidation, or a sale or transfer of all or substantially all of the assets to which this Agreement relates, provided that all obligations of Invivyd are assumed by the assignee. Upon any transfer or assignment by PHP of any of its obligations under this Agreement or any Work Order in accordance with this Section 9.6, PHP shall remain liable for the performance of any of the obligations so transferred or assigned by the assignee.

9.7 Entire Agreement. This Agreement constitutes the entire and only agreement between the parties with respect to the subject matter hereof, and supersedes all prior and contemporaneous negotiations, communications, representations, agreements and understandings of the parties with respect to the subject matter hereof.

9.8 No Modification. This Agreement may be changed only by a writing signed by an authorized representative of each party.

9.9 Notices. All notices required or permitted under this Agreement must be in writing and must be delivered to the addresses set forth in this Agreement by (a) personal, hand delivery, with receipt acknowledged, (b) certified or registered mail, return receipt requested, or (c) overnight carrier (with delivery confirmation). Notices to Invivyd will be marked "Attention: General Counsel." Either party may change its address for receipt of notices hereunder by notifying the other party in accordance with this Section 9.9.

9.10 Force Majeure. To the extent either party is delayed or hindered in or prevented from the performance of any of its obligations required under this Agreement by reasons of strike, lockouts, inability to procure materials, failure of power or restrictive government or judicial order or decrees, riots, insurrection, war, terrorism, acts of God, pandemics, epidemics or any similar reason or cause beyond the party's reasonable control, then performance of such obligations shall be excused for the duration of such delay, hindrance or prevention. The party whose performance is affected shall provide notice to the other party of the commencement and termination of the reason or cause. If such delay, hindrance or prevention continues in excess of thirty (30) days, either party may terminate the affected Services by providing written notice of such termination to the other party.

9.11 Waiver. The delay or failure of by either party to exercise or enforce any of its rights under this Agreement or any Work Order shall not constitute or be deemed to be a waiver of that party's right to enforce those rights, nor shall any single or partial exercise of any such rights preclude any other or further exercise thereof or the exercise of any other right. No waiver of any provision of this Agreement shall be effective unless it is in writing and signed by the party against which it is being enforced.

9.12 Severability. If any of the provisions of this Agreement are determined to be invalid, illegal or unenforceable, such provision shall be enforced only to the extent it is otherwise enforceable or is not illegal, and all such other provisions of this Agreement shall remain in full force and effect.

9.13 Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. Copies of signatures to this agreement delivered electronically (for example, in portable document format (.pdf) or by facsimile) shall have the same force and effect as an originally executed signature. Any fully executed copy of this Agreement will be deemed an original.

9.14 Electronic Records and Signature. The parties intend that federal and state laws validating their ability to form assent and commit electronically to be bound by the obligations described herein shall apply to this Agreement and any Work Order to the fullest extent possible. The parties further agree that an electronic signature is the legal equivalent of a manual signature on this Agreement or any Work Order, and that selecting "SIGN" constitutes their electronic signatures. The parties also agree that no certification authority or other third party verification is necessary to validate their electronic signatures and that the lack of such certification or third

party verification will not in any way affect the enforceability of their electronic signatures or any resulting contract between the parties.

9.15 Headings. The section headings are intended for convenience of reference only and are not intended to affect the meaning or interpretation of this Agreement.

9.16 Survival. The following Sections of this Agreement shall survive the expiration or early termination of this Agreement as allowed by law: 3.1.5 (Absence of Debarment), 5 (Proprietary Rights), 6 (Confidential Information), 7 (Indemnification), 8.1 (Term), 8.4 (Effect of Termination or Expiration), 9.2 (Non-solicitation), 9.3 (Remedies), 9.4 (Governing Law), 9.12 (Severability), and 9.15 (Headings).

[*Remainder of page intentionally left blank; signature page follows*]

The parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

INVIVYD, INC.	**POPULATION HEALTH PARTNERS, L.P.**
By /s/ David Hering	By: Population Health Partners GP, LLC
Print Name David Hering	By: /s/ Chris Cox Name: Chris Cox
Title CEO	Title: Managing Member

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY "[***]", HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Exhibit 10.21

WORK ORDER

THIS WORK ORDER, dated November 15, 2022 (this "**Work Order**") is by and between Invivyd, Inc. ("**Invivyd**" or the "**Company**") and **Population Health Partners, L.P.** ("**PHP"**), and upon execution will be incorporated into the Master Services Agreement, dated as of November 15, 2022 between Invivyd and PHP (the "**Agreement**"). Capitalized terms in this Work Order will have the same meaning as set forth in the Agreement. All terms and conditions of the Agreement will apply to this Work Order. To the extent that there is a conflict between a provision in this Work Order and a provision in the Agreement, the provisions in the Agreement shall govern. Invivyd hereby engages PHP as follows:

1. Services and Deliverables.

See Work Order, Exhibit A, attached

2. PHP Contacts.

[***]
[***]
[***]

3. Invivyd Contacts.

[***]
[***]

4. Cash compensation. The total cash compensation due to PHP for Services under this Work Order will not exceed $[***] without Invivyd's prior written approval.

Invoices should reference this Work Order or purchase order number provided to PHP and be emailed to AP@Invivyd.com.

The parties have caused this Work Order to be executed by their duly authorized representatives as of the date above.

INVIVYD, INC.	**POPULATION HEALTH PARTNERS, L.P.**
	By: Population Health Partners GP, LLC, its General Partner
By /s/ David Hering	By /s/ Chris Cox
Print Name David Hering	Print Name Chris Cox
Title CEO duly authorized	Title Managing Member duly authorized
Date 11/15/2022	Date 11/15/2022

WORK ORDER

EXHBIT A

[***]

Work Order Terms and Conditions

Term

This Work Order is effective for six (6) months from the Effective Date (the "**Term of the Work Order**"). Invivyd and PHP may extend the Term of the Work Order upon written agreement.

Fee Structure

Cash Fee

PHP's fee for the Services and Deliverables provided under this Work Order shall be $500,000 per month, payable in accordance with Payments and Reimbursements, below. For the avoidance of doubt, PHP's fee shall total an aggregate of $3,000,000 over the Term of the Work Order (the "**Aggregate Fee**"). In the event that (a) Invivyd terminates this Work Order for any reason other than material breach by PHP pursuant to the terms of the Agreement, or (b) PHP terminates this Work Order due to material breach by Invivyd pursuant to Section 8.2(a) or Section 8.2(b) of the Agreement, in each case, Invivyd shall pay to PHP the balance of the Aggregate Fee as of the date this Work Order is so terminated.

Payment and Reimbursements

PHP shall submit an invoice to Invivyd related to the Services and Deliverables provided to Invivyd and any appropriate, reimbursable expenses. Invivyd will issue payment for the invoice within forty-five (45) days of receipt of an invoice. All invoices shall be submitted and paid in accordance with Section 4 of the Agreement. Invivyd will reimburse PHP for actual reasonable, appropriate and documented business expenses in accordance with the terms of the applicable Work Order; provided, however, consistent with Section 4.2 of the Agreement, Invivyd will have no obligation to reimburse expenses that are (a) not approved in advance and in writing or (b) submitted to Invivyd more than ninety (90) days from the date such expense is incurred.

Equity Grant

Invivyd and PHP executed a Common Stock Purchase Warrant (the "**Warrant**") on November 15, 2022, in conjunction with this Work Order. The Warrant is attached as Exhibit 1 to this Work Order, and the terms of the Warrant are incorporated herein by reference.

WORK ORDER

EXHBIT 1

[Filed separately]

INVIVYD

SEPARATION AGREEMENT

October 12, 2022, as modified on November 11, 2022 Jane Henderson
[***]
[***]

Re: Separation Agreement

Dear Jane:

This letter sets forth the substance of the separation agreement (the "Agreement") which Invivyd, Inc. (the "Company") is offering to you to aid in your employment transition.

1. Separation. Your last day of work with the Company and your employment termination date will be November 30, 2022 (the "Separation Date"). From October 13, 2022 through the Separation Date, you will be on an "on call" status and only required to be available by telephone or video conference to respond to questions and/or provide information as requested by the Executive Leadership Team. As of October 13, 2022, you shall be deemed to have resigned from all officer and board member positions that you may hold with the Company or any of its respective subsidiaries and affiliates (if applicable).

2. Accrued Salary. On the Separation Date, the Company will pay you all accrued salary earned through the Separation Date, subject to standard payroll deductions and withholdings. You will receive these payments regardless of whether or not you sign this Agreement.

3. Severance Benefits. If you execute and do not revoke this Agreement, and comply with its terms, the Company will provide you or, in the event of your death prior to your Separation Date, to your estate, with the following benefits referred to herein as "Severance Benefits":

(a) **Cash Payment.** The Company will pay you, as severance, the equivalent of 9 months of your base salary in effect as of the Separation Date, subject to standard payroll deductions and withholdings. This amount will be paid in lump sum within thirty (30) days of the Separation Date (or such longer period as required in order for this Agreement to be enforceable, but in no event longer than sixty (60) days from the Separation Date).

(b) **Bonus.** The Company will pay you a lump sum payment in the amount of one hundred eighty-six thousand, six hundred seventy-three dollars and ninety-seven cents ($186,673.97), which reflects a payment prorated to the Separation Date, at one hundred (100) percent of your target annual bonus as determined by the compensation committee of the Company's board of directors, in its discretion with respect to the 2022 calendar year. For the avoidance of doubt, this determination has already been made and such amount is not subject to change (greater or less) in the event the Company modifies the corporate multiplier or target for employees at a later date. This amount shall be subject to applicable taxes and withholdings, and paid in a lump sum payment within thirty (30) days of the Effective Date of this Agreement.

(c) **Delayed Forfeiture of Time-Based Equity Awards.** Notwithstanding anything to the contrary in any Time-Based Equity Awards (as defined in the Employment Agreement (defined below)), the unvested portions of all Time-Based Equity Awards shall not terminate or be forfeited on the Separation Date, but rather shall remain outstanding until May 30, 2023, which is six (6) months after the Separation Date (the "Pre-CIC Protection Period"). If the Company has not, prior to the end of the Pre-CIC Protection Period, entered into a definitive agreement that, if closed, would result in a Change in Control (as defined in the Employment Agreement) (a "P&S Agreement") then the unvested portion of the Time-Based Equity Awards shall terminate and be forfeited as of the end of the Pre-CIC Protection Period. If the Company, prior to the end of the Pre-CIC Protection Period, enters into a P&S Agreement, then the Time-Based Equity Awards shall remain outstanding and, to the extent unvested, become fully vested upon a Change in Control resulting from such agreement, and all such awards that are assumed or continued in the Change in Control transaction shall remain outstanding until the later of (i) the end of the Pre-CIC Protection Period and (ii) ninety (90) days after such Change in Control. Unvested Time Based Equity Awards shall terminate and be forfeited if the Company abandons a sale of the Company as contemplated under the P&S Agreement entered into during the Pre-CIC Protection Period. No additional vesting of the Time-Based Equity Awards shall occur following the Separation Date except on account of a Change in Control during or after the Pre-CIC Protection Period as specifically provided herein. For the avoidance of doubt, any unvested Performance-Based Equity Awards (as defined in the Employment Agreement) shall terminate and be forfeited on the Separation Date unless otherwise provided by the terms of the Plan or the applicable award agreement. Notwithstanding anything herein to the contrary, no Time-Based Awards shall remain outstanding following the original expiration date of such award, as set forth in the applicable award agreement.

(d) **COBRA.** If you are eligible for and timely elect to continue your health insurance coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA") or the state equivalent, the Company will subsidize the cost of COBRA premiums for you and your eligible dependents, if any, until the earlier of (A) 9 months from the Separation Date, (B) the expiration of your eligibility for the continuation coverage under COBRA, or (C) such time as you become employed by another employer or self-employed through which you are eligible for health insurance (thereafter, you will be responsible for all COBRA premium payments, if any) (such period from your termination date through the earliest of (A) through (C), the "COBRA Payment Period"). You agree to promptly notify the Company if you become employed by another employer or self-employed through which you are eligible for health insurance during the COBRA

Payment Period. For purposes of this paragraph, references to COBRA premiums shall not include any amounts payable by you under an Internal Revenue Code Section 125 health care reimbursement plan. Notwithstanding the foregoing, if the Company determines, in its sole discretion, that the Company cannot provide the COBRA premiums without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), the Company may in lieu thereof pay you a taxable cash amount, which payment shall be made regardless of whether you elect health care continuation coverage (the "Health Care Benefit Payment"). The Health Care Benefit Payment shall be paid in monthly installments on the same schedule that the COBRA premiums would otherwise have been paid to you and shall be equal to the amount that the Company would have otherwise paid for COBRA premiums (which amount shall be calculated based on your COBRA premium for the first month of coverage), and shall be paid until the earlier of (i) the expiration of the COBRA Payment Period or (ii) the date you voluntarily enroll in a health insurance plan offered by another employer or entity.

4. **Benefit Plans.** Except as set forth in Section 3 above, if you are currently participating in the Company's group health insurance plans, your participation as an employee will end on the last day of the month in which separation occurs. Thereafter, to the extent provided by the federal COBRA law or, if applicable, state insurance laws, and by the Company's current group health insurance policies, you will be eligible to continue your group health insurance benefits at your own expense. Later, you may be able to convert to an individual policy through the provider of the Company's health insurance, if you wish.

Deductions for the 401(k) Plan will end with your last regular paycheck. You will receive information by mail concerning 401(k) plan rollover procedures should you be a participant in this program.

You may be eligible for unemployment insurance benefits after the Separation Date. Information concerning unemployment benefits will be provided under separate cover.

5. **Stock Options.** You were granted options to purchase shares of the Company's common stock, pursuant to the Company's 2021 Equity Incentive Plan and/or the 2020 Equity Incentive Plan (the "Plan"). Except as set forth in Section 3 above, under the terms of the Plan and your stock option grant, vesting will cease as of the Separation Date, all of your then vested options will remain outstanding for six (6) months after the Separation Date and all of your then unvested options will terminate and be forfeited as of the Separation Date.

6. **Other Compensation or Benefits.** You acknowledge that, except as expressly provided in this Agreement, you will not be entitled to nor shall you receive any additional compensation, severance or benefits after the Separation Date.

7. **Expense Reimbursements.** You agree that, within ten (10) days of the Separation Date, you will submit your final documented expense reimbursement statement reflecting all business expenses you incurred through the Separation Date, if any, for which you seek reimbursement.

Regardless of whether you execute this Agreement, The Company will reimburse you for reasonable business expenses pursuant to its regular business practice.

8. Return of Company Property. Within seven (7) calendar days of the Separation Date, you agree to return to the Company all Company documents (and all copies thereof) and other Company property that you have had in your possession at any time, including, but not limited to, Company files, notes, drawings, records, business plans and forecasts, financial information, specifications, computer-recorded information, tangible property (including, but not limited to, computers), credit cards, entry cards, identification badges and keys; and, any materials of any kind that contain or embody any proprietary or confidential information of the Company (and all reproductions thereof). Please coordinate return of Company property with Paul Grous, Senior Director, IT, Infrastructure and Security. **Receipt of the Severance Benefits described in Section 3 of this Agreement is expressly conditioned upon return of all Company Property.**

9. Confidential Information; Reaffirmation of Post-Termination Obligations. Both during and after your employment you acknowledge your continuing obligations under your Employee Proprietary Information and Inventions Assignment Agreement ("Restrictive Covenants Agreement") not to use or disclose any confidential or proprietary information of the Company and to refrain from certain solicitation activities. A copy of your Restrictive Covenants Agreement is attached hereto. By signing this Agreement, you hereby reaffirm your continuing obligations under the Restrictive Covenants Agreement to the Company, which may include, but are not limited to, non-competition and non-solicitation provisions. If you have any doubts as to the scope of the restrictions in your Restrictive Covenants Agreement, you should contact Jill Andersen, Chief Legal Officer immediately to assess your compliance. As you know, the Company will enforce its contract rights. Please familiarize yourself with the enclosed agreement which you signed. Confidential information that is also a "trade secret," as defined by law, may be disclosed (A) if it is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, in the event that you file a lawsuit for retaliation by the Company for reporting a suspected violation of law, you may disclose the trade secret to your attorney and use the trade secret information in the court proceeding, if you:
(A) file any document containing the trade secret under seal; and (B) do not disclose the trade secret, except pursuant to court order.

10. Mutual Non-Disparagement. You agree not to disparage the Company, and the Company's attorneys, directors, managers, partners, employees, agents and affiliates, in any manner likely to be harmful to them or their business, business reputation or personal reputation; provided that you may respond accurately and fully to any question, inquiry or request for information when required by legal process. You further agree that, by no later than the Effective Date, you shall delete or otherwise remove any and all disparaging public comments or statements that you made prior to the Effective Date about or relating to the Company, including, but not limited to, comments in online forums or on websites (including, but not limited to, Facebook,

Glassdoor, Yelp, and LinkedIn). Notwithstanding the foregoing, nothing in this Agreement shall limit your right to voluntarily communicate with the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, other federal government agency or similar state or local agency or to discuss the terms and conditions of your employment with others to the extent expressly permitted by Section 7 of the National Labor Relations Act. Likewise, the Company agrees not to disparage you, in any manner likely to be harmful to you or your reputation; provided that the Company may respond accurately and fully to any question, inquiry or request for information when required by legal process. The Company's obligations under this Section are limited to Company employees and/or directors with knowledge of this provision. The Company will provide knowledge of this provision to the Company's executive team (including the Chief Executive Officer, Chief Financial Officer, Chief Operating Officer, Chief Technology & Manufacturing Officer, Chief Legal Officer, Chief Development Officer, Chief Scientific Officer, and SVP, Human Resources) and the Company's Board of Directors.

11. Cooperation after Termination. You agree to cooperate fully with the Company in all matters relating to the transition of your work and responsibilities on behalf of the Company, including, but not limited to, any present, prior or subsequent relationships and the orderly transfer of any such work and institutional knowledge to such other persons as may be designated by the Company, by making yourself reasonably available during regular business hours.

12. Release. In exchange for the payments and other consideration under this Agreement, to which you would not otherwise be entitled, and except as otherwise set forth in this Agreement, you, on behalf of yourself and, to the extent permitted by law, on behalf of your spouse, heirs, executors, administrators, assigns, insurers, attorneys and other persons or entities, acting or purporting to act on your behalf (collectively, the "Employee Parties"), hereby generally and completely release, acquit and forever discharge the Company, its parents and subsidiaries, and its and their officers, directors, managers, partners, agents, representatives, employees, attorneys, shareholders, predecessors, successors, assigns, insurers and affiliates (the "Company Parties") of and from any and all claims, liabilities, demands, contentions, actions, causes of action, suits, costs, expenses, attorneys' fees, damages, indemnities, debts, judgments, levies, executions and obligations of every kind and nature, in law, equity, or otherwise, both known and unknown, suspected and unsuspected, disclosed and undisclosed, arising out of or in any way related to agreements, events, acts or conduct at any time prior to and including the execution date of this Agreement, including but not limited to: all such claims and demands directly or indirectly arising out of or in any way connected with your employment with the Company (including, but not limited to claims under any employment agreement that you may have with the Company) or the termination of that employment; claims or demands related to salary, bonuses, commissions, stock, stock options, or any other ownership interests in the Company, vacation pay, fringe benefits, expense reimbursements, severance pay, or any other form of compensation; claims pursuant to any federal, state or local law, statute, or cause of action; tort law; or contract law, including those relating to your Amended and Restated Employment Agreement, dated August 5, 2021 and the First Amendment to that agreement, dated March 18, 2022 (together, the "Employment

Agreement") (individually a "Claim" and collectively "Claims"). The Claims you are releasing and waiving in this Agreement include, but are not limited to, any and all Claims that any of the Company Parties:

- has violated its personnel policies, handbooks, contracts of employment, or covenants of good faith and fair dealing;

- has discriminated against you on the basis of age, race, color, sex (including sexual harassment), national origin, ancestry, disability, religion, sexual orientation, marital status, parental status, source of income, entitlement to benefits, any union activities or other protected category in violation of any local, state or federal law, constitution, ordinance, or regulation, including but not limited to: Title VII of the Civil Rights Act of 1964, the Civil Rights Act of 1866 (42 U.S.C. 1981), the Civil Rights Act of 1991, the Genetic Information Nondiscrimination Act, Executive Order 11246, which prohibit discrimination based on race, color, national origin, religion, or sex; the Americans with Disabilities Act and Sections 503 and 504 of the Rehabilitation Act of 1973, which prohibit discrimination against the disabled, the Age Discrimination in Employment Act (ADEA), which prohibits discrimination based on age, the Older Workers Benefit Protection Act, the National Labor Relations Act, the Lily Ledbetter Fair Pay Act, the anti-retaliation provisions of the Sarbanes-Oxley Act, or any other federal or state law regarding whistleblower retaliation; the Massachusetts Fair Employment Practices Act (M.G.L. c. 151B), the Massachusetts Equal Rights Act, the Massachusetts Equal Pay Act, the Massachusetts Privacy Statute, the Massachusetts Sick Leave Law, the Massachusetts Civil Rights Act, the Connecticut Fair Employment Practices Act, the Connecticut Free Speech Law, anti-retaliation provisions of the Connecticut Workers' Compensation Act, all as amended, and any and all other federal, state or local laws, rules, regulations, constitutions, ordinances or public policies, whether known or unknown, prohibiting employment discrimination;

- has violated any employment statutes, such as the WARN Act, which requires that advance notice be given of certain workforce reductions; the Employee Retirement Income Security Act of 1974 (ERISA) which, among other things, protects employee benefits; the Fair Labor Standards Act of 1938, which regulates wage and hour matters; the National Labor Relations Act, which protects forms of concerted activity; the Family and Medical Leave Act of 1993, which requires employers to provide leaves of absence under certain circumstances; the Fair Credit Reporting Act, the Employee Polygraph Protection Act, the Massachusetts Payment of Wages Act (M.G.L. c. 149 sections 148 and 150), the Massachusetts Overtime regulations (M.G.L. c. 151 sections 1A and 1B), the Massachusetts Meal Break regulations (M.G.L. c. 149 sections 100 and 101), the Connecticut Family and Medical Leave Act, the Connecticut Whistleblower Law, Connecticut's minimum wage and wage payment laws (Conn. Gen. Stat. Ann. §§ 31-58 to 31-

76m), all as amended, and any and all other federal, state or local laws, rules, regulations, constitutions, ordinances or public policies, whether known or unknown relating to employment laws, such as veterans' reemployment rights laws;

- has violated any other laws, such as federal, state, or local laws providing workers' compensation benefits, restricting an employer's right to terminate employees, or otherwise regulating employment; any federal, state or local law enforcing express or implied employment contracts or requiring an employer to deal with employees fairly or in good faith; any other federal, state or local laws providing recourse for alleged wrongful discharge, retaliatory discharge, negligent hiring, retention, or supervision, physical or personal injury, emotional distress, assault, battery, false imprisonment, fraud, negligent misrepresentation, defamation, intentional or negligent infliction of emotional distress and/or mental anguish, intentional interference with contract, negligence, detrimental reliance, loss of consortium to you or any member of your family, whistleblowing, and similar or related claims.

Notwithstanding the foregoing, other than events expressly contemplated by this Agreement you do not waive or release rights or Claims that may arise from events that occur after the date this waiver is executed or your right to enforce this Agreement. Also excluded from this Agreement are any Claims which cannot be waived by law, including, without limitation, any rights you may have under applicable workers' compensation laws and your right, if applicable, to file or participate in an investigative proceeding of any federal, state or local governmental agency. Nothing in this Agreement shall prevent you from filing, cooperating with, or participating in any proceeding or investigation before the Equal Employment Opportunity Commission, United States Department of Labor, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission or any other federal government agency, or similar state or local agency ("Government Agencies"), or exercising any rights pursuant to Section 7 of the National Labor Relations Act. You further understand this Agreement does not limit your ability to voluntarily communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information, without notice to the Company. While this Agreement does not limit your right to receive an award for information provided to the Securities and Exchange Commission, you understand and agree that, you are otherwise waiving, to the fullest extent permitted by law, any and all rights you may have to individual relief based on any Claims that you have released and any rights you have waived by signing this Agreement. If any Claim is not subject to release, to the extent permitted by law, you waive any right or ability to be a class or collective action representative or to otherwise participate in any putative or certified class, collective or multi-party action or proceeding based on such a Claim in which any of the Company Parties is a party. This Agreement does not abrogate your existing rights under any Company benefit plan or any plan or agreement related to equity ownership in the Company; however, it does waive, release and forever discharge Claims existing as of the date you execute this Agreement pursuant to any such plan or agreement. Additionally, nothing herein is intended

to, nor shall it, waive any rights you have to indemnification under any agreements with the Company.

13. Your Acknowledgments and Affirmations; Effective Date of Agreement; Schedule A. You acknowledge that you are knowingly and voluntarily waiving and releasing any and all rights you have under the ADEA, as amended. You also acknowledge and agree that (i) the consideration given to you in exchange for the waiver and release in this Agreement is above and beyond any wages or salary or other sums to which you are entitled from the Company under the terms of your employment with the Company or under any other contract or law, and (ii) that you have been paid for all time worked, have received all the leave, leaves of absence and leave benefits and protections for which you are eligible, and have not suffered any on-the-job injury for which you have not already filed a Claim. You affirm that all of the decisions of the Company Parties regarding your pay and benefits through the date of your execution of this Agreement were not discriminatory based on age, disability, race, color, sex, religion, national origin or any other classification protected by law. You affirm that you have not filed or caused to be filed, and are not presently a party to, a Claim against any of the Company Parties. You further affirm that you have no known workplace injuries or occupational diseases. You acknowledge and affirm that you have not been retaliated against for reporting any allegation of corporate fraud or other wrongdoing by any of the Company Parties, or for exercising any rights protected by law, including any rights protected by the Fair Labor Standards Act, the Family Medical Leave Act or any related statute or local leave or disability accommodation laws, or any applicable state workers' compensation law. You further acknowledge and affirm that you have been advised by this writing that: (a) your waiver and release do not apply to any rights or Claims that may arise after the execution date of this Agreement; (b) you have been advised hereby that you have the right to consult with an attorney prior to executing this Agreement; (c) you have been given a period of forty-five (45) days to consider this Agreement (although you may choose to voluntarily execute this Agreement earlier and if you do you will sign the Consideration Period waiver below);
(d) you have seven (7) days following your execution of this Agreement to revoke this Agreement; and (e) you should not sign this Agreement prior to the Separation Date and this Agreement shall not be effective until the date upon which the revocation period has expired unexercised (the "Effective Date"), which shall be the eighth day after this Agreement is executed by you. Failure to execute this Agreement within forty-five days of receiving the Agreement will render this Agreement null and void. If you revoke this Agreement, this Agreement shall become null and void.

You acknowledge that with your receipt of this Agreement you also received an "Age Discrimination in Employment Act Disclosure," attached as **Schedule A**, that contains information regarding (i) any class, unit, or group of individuals covered by the Company's reduction in force (the "Layoff"), any eligibility factors to receive Severance Benefits in connection with the Layoff, and any time limits applicable to the Layoff; and (ii) the job titles and ages of all individuals selected for the Layoff, and the ages of all individuals in the same job classification or organizational unit who are not selected for the Layoff.

14. No Admission. This Agreement does not constitute an admission by the Company of any wrongful action or violation of any federal, state, or local statute, or common law rights, including those relating to the provisions of any law or statute concerning employment actions, or of any other possible or claimed violation of law or rights.

15. Internal Revenue Code Section 409A. This Agreement is intended to comply with Section 409A of the Internal Revenue Code of 1986, as amended or an exemption thereunder and shall be construed and administered in accordance with Section 409A. Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. Any payments to be made under this Agreement upon a termination of employment shall only be made upon a "separation from service" under Section 409A. Notwithstanding the foregoing, the Company makes no representations that the payments and benefits provided under this Agreement comply with Section 409A and in no event shall the Company be liable for all or any portion of any taxes, penalties, interest or other expenses that may be incurred by Employee on account of non-compliance with Section 409A.

16. Breach. You agree that upon any breach of this Agreement you will forfeit all amounts paid or owing to you under this Agreement. Further, you acknowledge that it may be impossible to assess the damages caused by your violation of the terms of Sections 8, 9 and 10 of this Agreement and further agree that any threatened or actual violation or breach of those Sections of this Agreement will constitute immediate and irreparable injury to the Company. You therefore agree that any such breach of this Agreement is a material breach of this Agreement, and, in addition to any and all other damages and remedies available to the Company upon your breach of this Agreement, the Company shall be entitled to an injunction to prevent you from violating or breaching this Agreement. You agree that if the Company is successful in whole or part in any legal or equitable action against you under this Agreement, you agree to pay all of the costs, including reasonable attorneys' fees, incurred by the Company in enforcing the terms of this Agreement.

17. Miscellaneous. This Agreement, including any exhibits (such as the Restrictive Covenants Agreement), and your continuing obligations under the Employment Agreement, constitutes the complete, final and exclusive embodiment of the entire agreement between you and the Company with regard to this subject matter. It is entered into without reliance on any promise or representation, written or oral, other than those expressly contained herein, and it supersedes any other such promises, warranties or representations. This Agreement may not be modified or amended except in a writing signed by both you and a duly authorized officer of the Company. This Agreement will bind the heirs, personal representatives, successors and assigns of both you and the Company, and inure to the benefit of both you and the Company, their heirs, successors and assigns. If any provision of this Agreement is determined to be invalid or unenforceable, in whole or in part, this determination will not affect any other provision of this Agreement and the

provision in question will be modified by the court so as to be rendered enforceable. This Agreement will be deemed to have been entered into and will be construed and enforced in accordance with the laws of the State of Connecticut.

18. To ensure the rapid and economical resolution of disputes that may arise in connection with your employment with the Company, you and the Company agree that any and all disputes, claims, or causes of action, in law or equity, including but not limited to statutory claims (including, but not limited to, the Massachusetts Antidiscrimination Act, Mass. Gen. Laws ch.151B and the Massachusetts Wage Act, Mass. Gen. Laws ch. 149, the Connecticut Fair Employment Practices Act, the Connecticut Free Speech Law, anti-retaliation provisions of the Connecticut Workers' Compensation Act or statutory claims under the laws of the state in which you worked for the Company), arising from or relating to the enforcement, breach, performance, or interpretation of this Agreement, your employment with the Company, or the termination of your employment, shall be resolved, to the fullest extent permitted by law, by final, binding and confidential arbitration conducted by JAMS or its successor, under JAMS' then applicable rules and procedures for employment disputes (available upon request and also currently available at http://www.jamsadr.com/rules-employment-arbitration/). **You acknowledge that by agreeing to this arbitration procedure, both you and the Company waive the right to resolve any such dispute through a trial by jury or judge or administrative proceeding, except nothing herein shall prevent the Company from seeking injunctive relief in a court of competent jurisdiction related to confidentiality, restrictive covenants or trade secrets or disparagement.** You will have the right to be represented by legal counsel at any arbitration proceeding. The arbitrator shall: (a) have the authority to compel adequate discovery for the resolution of the dispute and to award such relief as would otherwise be permitted by law; and (b) issue a written statement signed by the arbitrator regarding the disposition of each claim and the relief, if any, awarded as to each claim, the reasons for the award, and the arbitrator's essential findings and conclusions on which the award is based. The arbitrator shall be authorized to award all relief that you or the Company would be entitled to seek in a court of law. The Company shall pay all JAMS arbitration fees in excess of the administrative fees that you would be required to pay if the dispute were decided in a court of law. Nothing in this Agreement is intended to prevent either you or the Company from obtaining injunctive relief in a court of competent jurisdiction to prevent irreparable harm pending the conclusion of any such arbitration. This Agreement was originally provided to you on October 12, 2022, and a revised Schedule A was provided to you on October 21, 2022. You agree that changes made to this Agreement since October 21, 2022 are not material and do not extend the Consideration Period.

If this Agreement is acceptable to you, please sign below and return the original to me **no later than December 5, 2022**. This Agreement will be null and void if we have not received your executed copy by that date.

I wish you good luck in your future endeavors. Sincerely,
Invivyd, Inc.

By: /s/ Julie Green
Julie Green
Senior VP, Human Resources

By signing below, you represent and warrant that you have full legal capacity to enter into this Agreement, you have carefully read and understand this Agreement in its entirety, have had a full opportunity to review this Agreement with an attorney of your choosing, and have executed this Agreement voluntarily, without duress, coercion or undue influence.

Agreed to and Accepted:

/s/ Jane Henderson

Name: Jane Henderson
Date: 11/11/2022

CONSIDERATION PERIOD

I, Jane Henderson, understand that I have the right to take at least 45 days to consider whether to sign this Agreement, which I received on October 21, 2022. If I elect to sign this Agreement before 45 days have passed, I understand I am to sign and date below this paragraph to confirm that I knowingly and voluntarily agree to waive the 45-day consideration period.

AGREED:

/s/ Jane Henderson
Signature

11/11/2022
Date

Schedule A

Exhibit 21.1

Invivyd, Inc.
Subsidiaries

1. Invivyd Security Corporation
2. Invivyd Switzerland GmbH
3. Invivyd Netherlands B.V.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-267643) and Form S-8 (Nos. 333-259008 and 333-264920) of Invivyd, Inc. of our report dated March 23, 2023 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 23, 2023

Exhibit 31.1

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

I, David Hering, certify that:

1. I have reviewed this Annual Report on Form 10-K of Invivyd, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2023

By: /s/ David Hering, M.B.A.

David Hering, M.B.A.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Frederick W. Driscoll, certify that:

1. I have reviewed this Annual Report on Form 10-K of Invivyd, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 23, 2023

By: /s/ Frederick W. Driscoll

Frederick W. Driscoll
Interim Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Invivyd, Inc. (the "Company") on Form 10-K for the period ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2023

By: /s/ David Hering, M.B.A.

David Hering, M.B.A.
Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Invivyd, Inc. (the "Company") on Form 10-K for the period ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 23, 2023

By: /s/ Frederick W. Driscoll

Frederick W. Driscoll
Interim Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.