

**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, 2023

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
(State or other jurisdiction of
incorporation or organization)

85-1403134
(I.R.S. Employer
Identification No.)

1601 Trapelo Road, Suite 178
Waltham, MA
(Address of principal executive offices)

02451
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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, 2023, 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 \$67.1 million based on the closing price of the registrant's common stock on June 30, 2023. 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 12, 2024 was 119,221,230.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its 2024 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, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

	<u>Page</u>
Cautionary Note Regarding Forward-Looking Statements	1
Summary of Risk Factors	3
PART I	
Item 1. Business	5
Item 1A. Risk Factors	33
Item 1B. Unresolved Staff Comments	98
Item 1C. Cybersecurity	98
Item 2. Properties	98
Item 3. Legal Proceedings	99
Item 4. Mine Safety Disclosures	99
PART II	
Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities	100
Item 6. [Reserved]	101
Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations	102
Item 7A. Quantitative and Qualitative Disclosures About Market Risk	115
Item 8. Financial Statements and Supplementary Data	115
Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure	116
Item 9A. Controls and Procedures	116
Item 9B. Other Information	116
Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections	116
PART III	
Item 10. Directors, Executive Officers and Corporate Governance	117
Item 11. Executive Compensation	117
Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters	117
Item 13. Certain Relationships and Related Transactions, and Director Independence	117
Item 14. Principal Accountant Fees and Services	117
PART IV	
Item 15. Exhibit and Financial Statement Schedules	118
Item 16. Form 10-K Summary	120

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:

- our plans to commercialize PEMGARDA™ (pemivibart), which received emergency use authorization (“EUA”) from the U.S. Food and Drug Administration (“FDA”) in March 2024, including our expectations about the potential market opportunity and our ability to meet anticipated initial demand for PEMGARDA;
- our expectation that PEMGARDA will be our first monoclonal antibody (“mAb”) in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution, and our plans to leverage our INVYMAB™ platform approach to periodically introduce new or engineered mAb candidates as the SARS-CoV-2 virus evolves over time, including our expectation that VYD2311, a mAb optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1, will be the next pipeline program to advance into clinical development;
- the anticipated timing, design, progress and results of preclinical studies and clinical trials of our product candidates, including statements regarding initiation or completion of studies or trials and related preparatory work, the period during which results of any studies or trials will become available, and potential regulatory submissions;
- our ability 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, and the potential of our pipeline of therapeutic candidates designed to protect vulnerable people from serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications;
- the anticipated 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 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 manufacturing capabilities and strategy;
- our ability to successfully commercialize our product candidates, if authorized or approved;
- our ability to leverage technology and our INVYMAB platform approach to identify and develop future product candidates;
- our expectation to apply our INVYMAB platform approach to produce lead molecules for other viral diseases, such as influenza;
- our estimates of our expenses, ongoing losses, future potential revenue, capital requirements and our need for or ability to obtain additional funding;
- our expectations regarding the anticipated timeline of our cash runway, and our ability to continue as a going concern; and
- our competitive position and the development of and projections relating to our competitors or our industry.

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

- Our financial condition raises substantial doubt regarding our ability to continue as a going concern.
- We have incurred significant losses since our inception. We may continue to incur losses 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 require additional funding through a combination of contribution from revenues, equity offerings, government or private-party grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements to finance our future operations. If we are unable to secure additional funding 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 variants 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 and to obtain and maintain authorization or approval of, and commercialize our product candidates.
- To date, we have received regulatory authorization for only one product candidate, PEMGARDA. All of our other product candidates, other than adintrevimab, are currently in preclinical development. If we are unable to successfully develop, receive regulatory authorization or approval 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/or treatment of relatively new 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 INVYTAB platform approach may not produce durable, broadly neutralizing, effective or safe mAbs in an adequate time period to address a changing virus. If we are unable to timely identify, develop, obtain and maintain authorization or approval for, and commercialize mAbs on a perpetual basis that keeps 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 Federal Food, Drug, and Cosmetic Act (the “FDCA”) permitting the FDA to authorize drugs and biologics for emergency use during the COVID-19 pandemic 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 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 authorization or approval.
- Lack of awareness or negative public opinion of mAb therapies and increased regulatory scrutiny of mAb 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.

Risks Related to the Manufacturing of our Product Candidates

- Monoclonal antibody therapies are complex and difficult to manufacture, and we currently rely on a contract manufacturer 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 currently depend on sole-source third-party suppliers and a single contract manufacturer for materials and services that are necessary for the conduct of preclinical studies, manufacture and testing of our product candidates for clinical trials and the commercialization of PEMGARDA, and the loss of these third-party suppliers or contract manufacturer or their inability to supply us with sufficient quantities of adequate materials and services, 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

- If the FDA revokes or terminates our EUA for PEMGARDA, we will be required to stop commercial distribution of PEMGARDA immediately unless we can obtain FDA approval for PEMGARDA under a traditional regulatory pathway, which is lengthy and expensive, which could harm our future business prospects.
- Even if any of our product candidates receive marketing authorization or approval, such as PEMGARDA, 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, due to the product profile, reimbursement dynamics or other reasons.
- If we are unable to build and maintain sales, marketing and distribution capabilities for PEMGARDA or any other product candidate that may receive regulatory authorization or approval, we may not be successful in commercializing PEMGARDA or such other product candidates if and when they are authorized or approved.
- The affected populations for our product candidates, including PEMGARDA, may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.
- Our mAb 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.
- Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business.

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. This lawsuit, 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 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

Inviydy, Inc. is a commercial-stage 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 proprietary INVYMAB™ platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering. INVYMAB is designed to facilitate the rapid, serial generation of new monoclonal antibodies (“mAbs”) to keep pace with evolving viral threats.

On March 22, 2024 we received emergency use authorization (“EUA”) from the U.S. Food and Drug Administration (“FDA”) for PEMGARDA™ (pemivibart) injection, for intravenous use, a half-life extended investigational mAb, for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2. We expect that PEMGARDA will be available for order in the U.S. imminently.

PEMGARDA is our first mAb in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution. As the SARS-CoV-2 virus evolves over time, we anticipate leveraging our INVYMAB platform approach to periodically introduce new or engineered mAb candidates, an approach that would be analogous to the periodic updates made to influenza and COVID-19 vaccines. In January 2024, we nominated VYD2311, a mAb optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1, as a drug candidate, and we expect it will be the next pipeline program to advance into clinical development. In addition to developing candidates for COVID-19, we expect to apply our INVYMAB platform approach to produce lead molecules for other viral diseases, such as influenza.

Prior to receiving the EUA for PEMGARDA in March 2024, we announced positive initial results from the ongoing CANOPY Phase 3 clinical trial of VYD222 in December 2023. The CANOPY clinical trial enrolled approximately 750 participants across two cohorts, including approximately 300 individuals who are significantly immunocompromised in Cohort A and approximately 450 individuals at risk of exposure to SARS-CoV-2 in Cohort B. Prior to commencing the CANOPY clinical trial, in June 2023, we announced that we reached general alignment with the FDA on a pathway to a potential EUA for VYD222 and anticipated follow-on mAb candidates designed to prevent COVID-19, which included the use of calculated serum neutralizing titers as a correlate of protection (surrogate of clinical efficacy) in an immunobridging approach to a pivotal clinical trial of VYD222. Based on FDA feedback, the use of a correlate of protection in an immunobridging approach to a pivotal EUA-directed clinical trial may be a reasonable approach for a new mAb candidate when clinical trial data from a “prototype” mAb is available, provided that the new mAb candidate: (1) is similar to the prototype mAb such that it leverages a consistent manufacturing platform and has limited structural and functional differences; and (2) has supportive nonclinical data, such as favorable *in vitro* neutralization data against currently circulating SARS-CoV-2 variants.

Globally, COVID-19 has caused millions of deaths and lasting health problems in many survivors and remains a significant global health concern, particularly for immunocompromised individuals. 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 immunocompromised, and combating this disease will require a variety of effective and safe prevention and treatment options for years to come. By leveraging our capabilities, which we have developed through our experience with adintrevimab and pemivibart and nearly four years in the COVID-19 space, we aim to develop a continuous repertoire of SARS-CoV-2 neutralizing mAbs to keep pace with viral evolution.

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. Our focus in recent months has been and will continue to be supporting the commercialization of PEMGARDA and establishing streamlined development pathways that could enable us to efficiently introduce new or engineered mAb candidates targeting SARS-CoV-2, leveraging our INVYMAB platform approach and previously generated safety and efficacy data from our clinical trials of adintrevimab and/or pemivibart.

We rely on partnerships, external consultants and contract research organizations (“CROs”) to conduct discovery, nonclinical, preclinical, clinical and commercial activities. Additionally, we rely on contract testing laboratories 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 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 strategy is to discover, develop and commercialize differentiated products that could be used for the prevention and/or treatment of viral 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 variants emerge. In order to achieve this goal, our strategy involves execution of the following key elements:

- **Successfully commercializing PEMGARDA in the U.S.** On March 22, 2024, we received an EUA from the FDA for PEMGARDA for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2. To support the commercialization of PEMGARDA, we have directly hired key leaders for our sales, marketing, market access, and medical affairs teams who have extensive experience commercializing products within the infectious diseases space. We are also leveraging contract organizations for certain field-based roles. We plan to concentrate initially on the healthcare practitioners and institutions who care for the highest risk immunocompromised adults and adolescents through a highly focused field sales organization, which can potentially expand over time to reach the additional healthcare practitioners and institutions who care for other groups of moderately to severely immunocompromised adults and adolescents. While we are currently focused on commercializing PEMGARDA in the U.S. with the commercial organization we have built, we continue to explore potential opportunities to expand our ability to serve vulnerable people through partnerships and collaborations.
- **Ensuring supply of drug product for PEMGARDA 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 PEMGARDA. We believe we have secured sufficient capacity for the anticipated initial demand for PEMGARDA. We continue to evaluate access to capacity at WuXi Biologics and other CDMOs so we can aim to meet potential future demand for PEMGARDA and future clinical product candidates.
- **Establishing streamlined development pathways that would allow us to fully leverage our INVYMAB platform approach to efficiently introduce new or engineered mAb candidates targeting SARS-CoV-2.** We continue to engage with the FDA with the aim of establishing expedited and replicable pathways for the authorization or approval of new or engineered SARS-CoV-2 mAbs that emerge from our INVYMAB platform approach. There are precedents for streamlined pathways in the influenza and COVID-19 vaccine spaces for leveraging existing safety and efficacy data to bridge quickly to new or modified vaccines. We expect that these discussions with the FDA will continue as we advance VYD2311, our next anticipated mAb candidate developed using our INVYMAB platform approach.
- **Advancing our INVYMAB platform approach and differentiated product candidates to address infectious diseases through internal research, in-licensing and leveraging collaborations.** Leveraging our INVYMAB platform approach which combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering, 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 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 can employ unique protein engineering strategies to enhance activity of our antibodies against circulating SARS-CoV-2 variants of concern ("VoCs"). With our cutting edge viral and epidemiological surveillance, we aim to stay ahead of potential future VoCs with our repertoire of broadly neutralizing mAbs. 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 PEMGARDA, which we expect to leverage to support our anticipated 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 recent estimates from the World Health Organization ("WHO"), there have been approximately 774 million cases of laboratory-confirmed COVID-19 and 7.0 million COVID-19-related deaths worldwide, with approximately 103 million laboratory-confirmed cases of COVID-19 and more than 1.2 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 continues to pose significant issues. A VoC is a variant designated by the 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 targeting SARS-CoV-2 previously authorized, prior to the EUA for PEMGARDA, have had their authorizations revoked in the U.S. due to loss of activity as new variants emerged.

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 effectiveness, and antiviral medications can have significant drug-drug interactions, particularly in the immunocompromised that can limit their utility. Monoclonal antibody therapies have the potential to provide vulnerable populations with additional protection from COVID-19.

mAbs for Prevention or Treatment of COVID-19 in the U.S.

As of the date of this report, no mAb has been approved in the U.S. for prevention (pre- or post-exposure) or treatment of COVID-19. Other than the EUA for PEMGARDA issued by the FDA in March 2024, the FDA previously 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 mAb products, casirivimab/imdevimab, bamlanivimab/etesevimab, sotrovimab, and bebtelovimab, 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. At this time none of these products, other than PEMGARDA, are authorized for use in prevention or treatment of COVID-19 in the U.S. due to loss of activity as new variants emerged. 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 mAbs 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 mAb 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 or modify their Fc-mediated innate immune effector function. Additionally, we profile the activity of our candidates expressed in 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 new, expedited approaches and pathways are needed across nonclinical, 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, and PEMGARDA, 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 mAbs with robust safety and efficacy data generated across the class. We expect that these data will enable the continued application of surrogate endpoints in future development programs, an approach that was leveraged in our CANOPY clinical trial of VYD222 with the use of calculated serum neutralizing antibody titers as a correlate of protection. 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.

Emergency Use Authorization Environment in the U.S.

Under Section 564 of the FDCA, the FDA Commissioner has the authority to authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances after the Secretary of the U.S. Department of Health and Human Services (“HHS”) has made a declaration of an emergency or threat justifying authorization of emergency use. On January 31, 2020, the Secretary of HHS issued a declaration of a public health emergency related to COVID-19 under Section 319 of the Public Health Service Act (the “PHS Act”). On February 4, 2020, the Secretary of HHS determined pursuant to his authority under Section 564 of the FDCA that COVID-19 represented a public health emergency with significant potential to affect national security or the health and security of U.S. citizens living abroad. Following this determination, on March 27, 2020, the Secretary of HHS declared that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic, subject to the terms of any authorization issued by the FDA.

Although the Biden Administration allowed the COVID-19 public health emergency declared by HHS under Section 319 of the PHS Act to expire on May 11, 2023, this did 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 determinations and declarations issued pursuant to Section 564 of the FDCA, including the EUA declaration on March 27, 2020, which remains in effect unless or until the Secretary of HHS terminates such declaration. If an EUA declaration is terminated, the 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.

Unlike previous EUAs for COVID-19, where products were available via an Advance Purchase Agreement with the U.S. federal government, PEMGARDA will follow a traditional commercial distribution model. In the traditional commercial

model, customers purchase the product directly from wholesalers and/or distributors and the product is shipped to the various sites of care, including provider institutions and clinics that bill health insurance plans for the product.

Addressable Patient Populations

Pre-Exposure Prophylaxis

Based on our market research and internal analysis, we believe that there are more than 9 million immunocompromised people, with varying degrees of immune compromise, in the U.S. alone who may not adequately respond to COVID-19 vaccination, increasing their risk for severe COVID-19.

The total addressable market in the U.S. for PEMGARDA is limited to the population that falls within the product's authorized use, specifically certain adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Of the various groups with moderate-to-severe immune compromise, we believe that there are approximately 485,000 people in the highest risk group, such as solid organ transplant recipients and those with certain hematological/lymphatic cancers, including stem cell transplant recipients.

In an EUA environment, the Healthcare Provider and Patient Fact Sheets specify the patient populations eligible to receive an authorized product, such as PEMGARDA, and utilization is bound by these specifications.

Treatment

We believe that there are still gaps in COVID-19 treatment alternatives. For instance, significant drug-drug interactions can limit the utility of some oral antivirals as a treatment option for immunocompromised people or others who are taking certain medications. While COVID-19 prevention is our current focus, and PEMGARDA is not authorized for use for treatment of COVID-19 or for post-exposure prophylaxis of COVID-19, we believe there could be opportunities to further explore the development of mAbs for the treatment of COVID-19.

Pediatrics

Although children are at lower risk of developing severe COVID-19 compared to adults, a subset of children experience severe disease and poor outcomes, such as multisystem inflammatory syndrome and long COVID. Safe and effective therapies are needed to prevent disease and hospitalization in high-risk children including these complications. 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.

Pipeline Overview

With our INVYMAB platform approach, we aim to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats. Leveraging state-of-the-art viral surveillance, predictive modeling, and advanced antibody engineering techniques, we have generated a pipeline of therapeutic candidates designed to protect vulnerable people from serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications.

PEMGARDA is our first mAb in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution. As the virus evolves over time, we anticipate periodically introducing new or engineered mAb candidates, an approach that would be analogous to the periodic updates made to influenza and COVID-19 vaccines. We expect that VYD2311 will be the next anti-SARS-CoV-2 mAb candidate that we advance into clinical development. VYD2311 is optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1.

Beyond PEMGARDA and VYD2311, we have additional anti-SARS-CoV-2 mAb candidates in discovery and pre-clinical characterization. Our robust pipeline reflects our strategy to continuously discover and engineer new candidates that can be leveraged to keep pace with viral evolution.

PROGRAMS	TARGET	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	AUTHORIZED	STATUS
COVID-19							
Pemivibart	Pre-exposure prophylaxis (prevention)						Received emergency use authorization (EUA) from the U.S. FDA
VYD2311	Prevention or treatment						Preparing for initiation of IND-enabling studies
COVID candidate #3	Prevention or treatment						Engineering variant matching
COVID candidate #4	Prevention or treatment						Engineering variant matching
Adintrevimab	Prevention or treatment						Trials concluded; EUA filing dependent on variant susceptibility
OTHER VIRAL DISEASES							
Influenza	Prevention						Early discovery

All antibodies listed are investigational therapies and have not been approved for use by any regulatory authority.

PEMGARDA

PEMGARDA (pemivibart) injection, for intravenous use received EUA from the FDA in March 2024 for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or had recent known exposure to a person infected with SARS-CoV-2.

Per the PEMGARDA Fact Sheet for Healthcare Providers, medical conditions or treatments that may result in moderate-to-severe immune compromise and an inadequate immune response to COVID-19 vaccination include:

- 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 immunosuppressive 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 $<200/\text{mm}^3$, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- 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)

PEMGARDA is not authorized for treatment of COVID-19, or for post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2. PEMGARDA has not been approved, but has been authorized for emergency use by the FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg). The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the FDCA, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner.

Based on the FDA's review of the totality of scientific evidence available, the FDA determined that it is reasonable to believe that PEMGARDA may be effective for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents, as described in the EUA, and that when used under the conditions described in the EUA, the known and potential benefits of PEMGARDA outweigh the known and potential risks of such product. To support the EUA for PEMGARDA, an

immunobridging approach was used to determine if PEMGARDA may be effective for pre-exposure prophylaxis of COVID-19. Immunobridging is based on the serum neutralization titer-efficacy relationships identified with other neutralizing human mAbs against SARS-CoV-2. This includes adintrevimab, the parent mAb of pemivibart, and other mAbs that were previously authorized for EUA. The CANOPY clinical trial was designed to utilize current relevant SARS-CoV-2 variants in the analyses of neutralizing titers. The most relevant SARS-CoV-2 variant circulating in the U.S. at the time of the analysis (JN.1) was selected as the variant for the analysis of the primary immunobridging endpoint. Initial immunobridging data from the immunocompromised cohort showed that immunobridging was established in the CANOPY clinical trial and that the calculated serum neutralizing antibody titers against JN.1 were consistent with the titer levels associated with efficacy in prior clinical trials of adintrevimab and other mAb products previously authorized for the prevention of COVID-19.

There are limitations of the data supporting the benefits of PEMGARDA. Evidence of clinical efficacy for other neutralizing human mAbs against SARS-CoV-2 was based on different populations and SARS-CoV-2 variants that are no longer circulating. Additionally, the variability associated with cell-based EC₅₀ value determinations, along with limitations related to pharmacokinetic data and efficacy estimates for the mAbs in prior clinical trials, impact the ability to precisely estimate protective titer ranges.

With regards to the safety profile, anaphylaxis has been observed with PEMGARDA and the PEMGARDA Fact Sheet for Healthcare Providers includes a boxed warning for anaphylaxis. The most common adverse events (all grades, incidence $\geq 2\%$) observed in participants who have moderate-to-severe immune compromise treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea.

Following the recent authorization of PEMGARDA, we expect that product will be available for order in the U.S. imminently. We plan to concentrate initially on the healthcare practitioners and institutions who care for the estimated 485,000 highest risk moderately to severely immunocompromised adults and adolescents through a highly focused field sales organization which can potentially expand over time to reach additional healthcare practitioners and institutions who care for other groups of moderately to severely immunocompromised adults and adolescents. We have directly hired key leaders for our sales, marketing, market access, and medical affairs teams, in addition to leveraging contract organizations for certain field-based roles.

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 PEMGARDA and VYD2311. PEMGARDA and VYD2311 are 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 PEMGARDA, VYD2311 and other product candidates. This license enables cell line and manufacturing process transfer to additional contract manufacturers.

We have devoted and expect to continue to devote significant resources to the manufacture of PEMGARDA, and we expect to have sufficient clinical supply to support our ongoing clinical trial needs and sufficient commercial supply to meet anticipated initial demand for PEMGARDA.

Foreign contract manufacturing organizations, including WuXi Biologics, may be subject to U.S. legislation, including the proposed BIOSECURE Act, investigations, sanctions, trade restrictions, and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay or impact clinical trials, or delay procurement of

commercial supply. Accordingly, we continue to evaluate access to capacity at WuXi Biologics, as well as other CDMOs so we can aim to meet potential future demand for PEMGARDA and future clinical product candidates.

Our Relationship with Adimab

Since our founding in June 2020, we have focused on the development of mAbs 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—Adimab Platform Transfer Agreement.”

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, 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 also granted us 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. We are 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. 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.

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 \$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. Through December 31, 2023, we had made aggregate milestone payments of \$11.1 million to Adimab under the Adimab Assignment Agreement. We are also obligated to pay Adimab royalties of a mid-single-digit percentage based on net sales of any Products, beginning upon the first commercial sale of a Product in accordance with the Adimab Assignment Agreement. 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 (the “Royalty Term”).

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. We may terminate the Adimab Assignment 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 if we materially breach, and do not cure, our 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.

Through December 31, 2023, we had made aggregate payments of \$13.7 million to Adimab under the Adimab Assignment Agreement, inclusive of the aforementioned milestone payments.

Adimab Collaboration Agreement

In May 2021, we entered into a Collaboration Agreement with Adimab, as amended in November 2022 and September 2023 (the “Adimab Collaboration Agreement”), for the discovery and optimization of proprietary antibodies as potential therapeutic product candidates. Under the Adimab Collaboration Agreement, we could 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 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 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 our 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 for the development, manufacture and commercialization of 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 optioned research program.

Under the Adimab Collaboration Agreement, we agreed to pay Adimab a quarterly fee of \$1.3 million, which could be cancelled at our option at any time. For so long as we were paying such quarterly fee (or earlier if (i) 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 agreed not to assist or direct certain third parties to discover or optimize antibodies intended to bind to coronaviruses or influenza viruses. Under the Adimab Collaboration Agreement, we could also elect to decrease the scope of Adimab’s exclusivity obligations and obtain a corresponding decrease in the quarterly fee. In December 2023, we elected to decrease the scope of Adimab’s exclusivity obligations to cover only coronaviruses and obtained a corresponding decrease in the quarterly fee, and we are now obligated to pay Adimab a quarterly fee of \$0.6 million starting in the first quarter of 2024.

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 Adimab Collaboration Agreement that achieves such milestones. We are 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, 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 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 periods.

Through December 31, 2023, we had made aggregate payments of \$17.1 million to Adimab under the Adimab Collaboration Agreement. As of December 31, 2023, \$0.7 million was due to Adimab by us.

Adimab Platform Transfer Agreement

In September 2022 (the “Adimab Platform Transfer Agreement 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 has been 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 Adimab Platform Transfer Agreement Effective Date, which allows 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 became due in September 2023 and was paid in October 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, 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, 2023, we had made aggregate payments of \$5.0 million to Adimab under the Adimab Platform Transfer Agreement.

Population Health Partners

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 for an initial term of one year. The PHP MSA renews for subsequent periods, until terminated 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 was effective for six months from the PHP Effective Date and terminated in accordance with its terms in May 2023. 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 Limited Partner of PHP, respectively.

As compensation for the services and deliverables under the PHP Work Order, we paid 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 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 was 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 either the achievement of corresponding market capitalization targets or a consummation of a fundamental transaction (as defined in the PHP Warrant).

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 in February 2023 and March 2024. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments” and “—Other Commitments.”

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 authorizations or approvals, and commercializing authorized or 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 but may not be limited to, AstraZeneca plc, 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).

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 PEMGARDA or our other product candidates. Some of our competitors have already previously obtained EUAs from the FDA for the prevention of COVID-19 in immunocompromised patients and the treatment of mild to moderate COVID-19 in high-risk patients, and others in the future may obtain EUAs from the FDA or other regulatory approval or authorization more rapidly than we may, which could result in our competitors establishing a strong market position. The key competitive factors affecting the success of PEMGARDA and our other product candidates, if authorized or 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 U.S. Patent and Trademark Office (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.

Patents

As of March 12, 2024, 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, Japan, Mexico, and Taiwan. This patent family is directed to broadly neutralizing anti-coronavirus antibodies, including ADG20 (adintrevimab) and ADG10, and uses thereof. These patents and patent applications and any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon such applications, if issued, are expected to expire in 2041, without taking into account any possible patent term adjustment or extension.

As of March 12, 2024, 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 12, 2024, we own two additional patent families. The first patent family is directed to additional broadly neutralizing anti-coronavirus antibodies, combination therapies, and uses thereof, and includes one PCT application and one foreign patent application in Taiwan. 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 one PCT patent application. 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.

Trademarks

Certain features of our business and product candidates are protected by trademarks. As of March 12, 2024, we have filed trademark applications for marks including INVIVYD, PEMGARDA and INVYMAB, as well as logos and certain stylized versions of these word marks. Applications have been filed inside and outside of the United States, and while many are still pending, a number of registrations have been issued in Australia, China, European Union, Japan, New Zealand, Norway, Switzerland, and United Kingdom.

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 biological product candidates. FDA licensure also must be obtained before biologics can be marketed. Additionally, although significant regulatory aspects in the European Union are addressed in a centralized way through the European Medicines Agency (the “EMA”) and the European Commission, 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 authorizations and/or 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 biological 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;
- manufacture and preparation of clinical trial material in accordance with applicable current Good Manufacturing Practices (“cGMP”);
- submission to the FDA of an application for an Investigational New Drug Application (“IND”), which contains, among other data and information, nonclinical testing results and provides a basis for the FDA to conclude that there is an adequate basis for testing the investigational product 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 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 biological 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 biological product candidate is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the biological product candidate’s identity, strength, quality and purity;

- potential FDA audit of the nonclinical and clinical trial 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 biological 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 trial 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 trial, including, for example, if the FDA questions 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 biological 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 biological product candidate to healthy volunteers or subjects under the supervision of qualified investigators, generally physicians not employed by or under the trial 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 cGCP and FDA regulations, 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 potential benefits, if any. 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 trials conducted under an IND must meet the same requirements that apply to trials 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 BLA 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, the foreign data are applicable to the U.S. population and U.S. medical practice, 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 biological product candidate is initially introduced into healthy human subjects and tested for safety. In the case of some biological product candidates for rare diseases, the initial human testing is often conducted in the intended patient population. 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 biological product candidate.
- **Phase 2.** The biological 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 biological product candidate for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- **Phase 3.** The biological 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) often at geographically

dispersed clinical trial sites. These clinical trials are intended to establish the overall risk-benefit ratio of the biological 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 a positive risk-benefit assessment 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, the sponsor or the sponsor's data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the biologic has been associated with a 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 biological 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 that have reached certain development milestones must also have a publicly available policy on evaluating and responding to requests for expanded access.

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, clinical trials, 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 six months after the 60-day filing date, or eight 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 mitigate certain specific safety risks 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 FDA will not approve the application in its present form. 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, nonclinical 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, or other safety information 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-approval 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 trials or 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 60 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 nonclinical 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 known and potential benefits of the product outweigh the known and potential 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 a BLA, EUAs nevertheless require the development and submission of data to satisfy the relevant FDA standards, and EUA holders must comply with a number of ongoing compliance obligations.

The FDA expects EUA holders to work toward submission of full applications, such as a BLA or a New Drug Application, as soon as possible. An EUA is also subject to additional conditions and restrictions that may be 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.

Under Section 564 of the FDCA, the FDA Commissioner has the authority to authorize the emergency use of an unapproved medical product or an unapproved use of an approved medical product for certain emergency circumstances after the Secretary of HHS has made a declaration of an emergency or threat justifying authorization of emergency use. On January 31, 2020, the Secretary of HHS issued a declaration of a public health emergency related to COVID-19 under Section 319 of the PHS Act. On February 4, 2020, the Secretary of HHS determined pursuant to his authority under Section 564 of the FDCA that COVID-19 represented a public health emergency with significant potential to affect national security or the health and security of U.S. citizens living abroad. Following this determination, on March 27, 2020, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, subject to the terms of any authorization issued by the FDA.

Although the Biden Administration allowed the COVID-19 public health emergency declared by HHS under Section 319 of the PHS Act to expire on May 11, 2023, this did 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 determinations and declarations issued pursuant to Section 564 of the FDCA, including the EUA declaration on March 27, 2020, which remains in effect unless or until the Secretary of HHS terminates such declaration. If an EUA declaration is terminated, the 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-Authorization or 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 authorization or 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 risk-benefit profile 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 authorization or 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 and biological 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 often inspects equipment, facilities and manufacturing processes before authorization or approval and conducts periodic re-inspections after authorization or approval. If, after receiving authorization or approval, a company makes a material change in manufacturing equipment, location, or process (all of which are, to some degree, incorporated in the EUA or BLA), additional regulatory review and approval may be required. Failure to comply with applicable cGMP requirements or the conditions of the product's authorization or 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 authorization or 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 or an EUA is issued, 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-patient advertising, promotion to healthcare practitioners and payors, the prohibition on promoting products for uses or patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. 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 HHS, 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, authorization or approval process or after authorization or approval may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to authorize or approve pending applications, withdrawal of an authorization or 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 EUAs or approved BLAs 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, including as implemented in the United Kingdom (collectively, "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" – certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function 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-approval 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 trial, 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 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 may be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials 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 authorization or approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials.

In the European Union, for example, the Clinical Trials Regulation (Regulation (EU) No 536/2014) (the “Current CTR”) came into effect on January 31, 2022, and is directly applicable in all the European Union Member States, repealing the previous

Clinical Trials Directive (Directive 2001/20/EC) (the “Previous CTD”) which previously regulated clinical trials in the European Union. Prior to the Current CTR, clinical trial sponsors had to submit clinical trial applications (“CTAs”) to each country’s national health authority and independent ethics committees, much like the FDA and the IRB, respectively. The Current CTR enables sponsors to submit one application via an online platform known as the Clinical Trials Information System (“CTIS”) for authorization to run a clinical trial in several European countries. The evaluation and authorization of clinical trials, however, remains a responsibility of each country. The use of the CTIS is mandatory for CTAs submitted on or after January 31, 2023. Clinical trials authorized under the Previous CTD before January 31, 2023, can continue without any discontinuation or hold requirements. However, beginning on January 31, 2025, such clinical trials will need to be transitioned to the Current CTR framework, including the requirement to record information on the trials in the CTIS. An application to transition ongoing trials from the Previous CTD to the Current CTR must be submitted and authorized in time before the end of the transitional period. The Current CTR harmonizes the assessment and supervision processes for clinical trials throughout the CTIS, which contains a centralized European Union portal and database. The main characteristics of the Current CTR 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.

Once a CTA is approved in accordance with the applicable requirements, clinical trial development may proceed. The requirements and processes governing the conduct of clinical trials are overall harmonized at the European Union level. In all cases, the clinical studies are conducted in accordance with cGCP, applicable regulatory requirements and applicable ethical principles.

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, as of January 1, 2024, Great Britain implemented the international recognition procedure (the “IRP”) which provides for an expedited authorization procedure for applicants that have already received an authorization for the same product from one of MHRA’s specified reference regulators (each, an “RR”). A positive opinion from the CHMP is considered for this purpose as an “RR” authorization”. The IRP allows the MHRA to take into account the expertise and decision-making of trusted regulatory partners, including the EMA. The MHRA will conduct a targeted assessment of IRP applications but retains the authority to reject applications. Northern Ireland continues to be covered by the marketing authorizations granted by the European Commission. However, the new Windsor Framework agreed to by the United Kingdom and European Union, effective as of January 1, 2025, brings new measures. Prior to January 1, 2025, marketing authorizations issued by the European Commission through the centralized procedure will continue to be applicable in Northern Ireland. Beginning on January 1, 2025, medicinal products intended for the United Kingdom market (including Northern Ireland) must be authorized by the MHRA and bear a clear “UK only” label.

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 on the federal level by the Centers for Medicare & Medicaid Services (“CMS”), an agency within HHS that administers the Medicare program, and, on the state level, by state Medicaid programs. CMS and state Medicaid programs decide whether and to what extent products will be covered and reimbursed under Medicare and Medicaid, and private payors tend to follow Medicare and Medicaid 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. 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 product 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 authorized or 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 authorized or 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 or reward 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. This statute has been interpreted to apply to arrangements between pharmaceutical companies on one hand and prescribers, patients, purchasers, and formulary managers on the other. Liability under the Anti-Kickback Statute may be established without proving actual knowledge of the statute or specific intent to violate it. 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 civil False Claims Act. Violations of this law may be punishable by up to ten years in prison, criminal fines, damages, administrative civil money penalties, and the potential for exclusion from participation in federal healthcare programs. 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, which prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, claims for payment of government funds, including Medicare and Medicaid, 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. Actions under the False Claims Act may be brought by the federal government or as a *qui tam* action by a private individual in the name of the government. Penalties for a False Claims Act violation may include three times the actual damages sustained by the government, plus significant civil penalties for each separate false or fraudulent claim, and the potential for exclusion from participation in federal healthcare programs.
- 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 and investment 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 United Kingdom 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 authorized or approved products. While Medicare laws and regulations apply only to 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 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 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. The ACA also 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 ACA, as amended by the Bipartisan Budget Act of 2018, requires manufacturers participating in Part D to provide a 70% point-of-sale discount on the negotiated price of prescriptions filled by beneficiaries in the Medicare Part D coverage gap. The Inflation Reduction Act of 2022 ("IRA") sunsets the Part D coverage cap discount program and replaces it 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.

Additional regulations governing the ACA have been finalized. 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% through the first 7 months of 2032. The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, currently set at 100% of a drug's AMP, for single-source and innovator multiple-source drugs, as of January 1, 2024. Additionally, the American Taxpayer Relief Act 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.

The IRA, 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. The IRA also prohibits Medicare Part D plans from imposing cost-sharing for certain vaccines that are recommended by the Advisory Committee on Immunization Practices. 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, IRA or their implementing regulations or guidance, 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.

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 2032 and it is uncertain if and how it will be implemented.

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 authorized or approved, or additional pricing pressures. Further, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic.

Employees and Human Capital Resources

As of February 1, 2024, we had 94 full-time employees and one part-time employee. Of our 95 full- and part-time employees, approximately 20 have Ph.D. or M.D. degrees and 62 are engaged in research and development activities. We have a hybrid workforce, with approximately 51% of our employees based in Massachusetts, 11% based in California, 7% based in New Jersey, 5% based in North Carolina, and the remaining 26% 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

We operate as a hybrid company with employees working at our corporate headquarters in Waltham, Massachusetts, our laboratory in Newton, Massachusetts and remotely.

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 hybrid working approach is adequate to meet our ongoing needs, and that, if we require additional 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

Our financial condition raises substantial doubt regarding our ability to continue as a going concern.

Our consolidated financial statements have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets, and the satisfaction of liabilities and commitments in the ordinary course of business. Based on our current operating plans and excluding any contribution from revenues or external financing, however, we believe that our existing cash and cash equivalents will not be sufficient to fund our operating expenses and capital expenditure requirements for more than one year from the issuance of the consolidated financial statements for the year ended December 31, 2023. Specifically, based on our current operating plans and excluding any contribution from revenues or external financing, we believe these funds will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. As a result, we have determined that there is substantial doubt regarding our ability to continue as a going concern, and our independent registered public accounting firm has included in its audit opinion for the year ended December 31, 2023, an explanatory paragraph about such substantial doubt regarding our ability to continue as a going concern.

The substantial doubt regarding our ability to continue as a going concern may adversely affect our stock price and our ability to raise capital necessary to execute our current operating plans. If we are unable to obtain additional capital, we may not be able to continue our operations on the scope or scale as currently conducted, and that could have a material adverse effect on our business, results of operations, financial condition, and ability to operate as a going concern.

We have incurred significant losses since our inception. We may continue to incur losses and may never achieve or maintain profitability.

Since our inception, we have incurred significant losses, and we may continue to incur significant expenses and operating losses for the foreseeable future. Our net losses were \$198.6 million and \$241.3 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of \$732.1 million. Since our inception, we have financed our operations primarily with net proceeds from several public and private offerings of our capital stock. In March 2024, we received an EUA from the FDA for PEMGARDA, but have no other products authorized or approved for commercialization and have not yet generated any revenue from product sales to date.

We may continue to incur significant expenses and operating losses. Our net losses may fluctuate significantly from quarter to quarter and year to year. Our expenses could increase substantially as we:

- commercialize PEMGARDA;
- initiate and conduct clinical trials of our product candidates;
- develop product candidates in new indications or patient populations;
- advance 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 regulatory authorizations or approvals and coverage and reimbursement for our product candidates, if authorized or approved;
- acquire or in-license other product candidates, intellectual property and/or technologies;
- validate our commercial-scale cGMP manufacturing processes, and manufacture material under cGMP at our contracted manufacturing facilities for clinical trials and potential commercial sales;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;

- maintain and expand a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory authorization or approval;
- hire and retain personnel, including research, clinical, development, manufacturing quality control, quality assurance, regulatory, scientific, and other personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

Although we have received an EUA from the FDA for PEMGARDA, to date, we have not yet generated any revenue from product sales. Our ability to execute our current business strategy and become and remain profitable is heavily dependent on our ability to develop and commercialize product candidates that generate significant revenue. This will require us to be successful in a range of challenging activities on a timeline that keeps pace with viral evolution, including completing preclinical testing and clinical trials of our product candidates, validating manufacturing processes, obtaining regulatory authorization or approval, and manufacturing, distributing, marketing, and selling any products for which we obtain regulatory authorization or approval, as well as discovering and developing additional product candidates. We may never succeed in these activities and, even if we do, may never generate 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 authorizations or 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, 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 capital raising. To date, we have received regulatory authorization for only one product candidate, PEMGARDA, which received an EUA from the FDA in March 2024 and which we are currently focused on commercializing in the U.S. We have not historically demonstrated our ability to successfully conduct sales and marketing activities necessary for commercialization, and we may not be successful in doing so. Additionally, it is uncertain as to if or when we may submit a request for an EUA or application for regulatory approval for any other product candidate, and we may not be successful in receiving any 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. Having received an EUA from the FDA for PEMGARDA, we are transitioning from a company with a research and clinical focus to a commercial company, and we may not be successful in such a transition.

We will require additional funding through a combination of contribution from revenues, equity offerings, government or private-party grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements to finance our future operations. If we are unable to secure additional funding 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, although we received an EUA from the FDA for PEMGARDA in March 2024, we may continue to incur significant expenses and operating losses 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. Aside from any revenue generated from sales of PEMGARDA, additional revenue, if any, will be derived from sales of products that may not be commercially available for a number of years, if at all. Furthermore, even if we obtain regulatory authorization or approval for a product candidate that we develop, such as PEMGARDA, or otherwise acquire, we may incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Accordingly, until such time, if ever, as we can generate substantial revenue from sales of authorized or approved products, we expect to finance our operations through a combination of equity offerings, government

or private-party funding or grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements.

As of December 31, 2023, we had cash and cash equivalents of \$200.6 million. Based on our current operating plans and excluding any contribution from revenues or external financing, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter 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 and cash equivalents to fund research and development, manufacturing supply and commercialization costs for our product candidates, the development of additional programs in our pipeline and for working capital and other general corporate purposes. The timing and amount of our funding requirements will depend on many factors, including:

- the revenue received from sales of PEMGARDA and any other product candidates for which we receive future regulatory authorization or approval;
- the rate of progress in the development of our product candidates;
- the scope, progress, results and costs of discovery, nonclinical 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, intellectual property and/or technologies;
- 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 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 build and maintain a commercial infrastructure for product candidates for which we obtain regulatory authorization or approval;
- the timing and costs of securing sufficient manufacturing capacity for clinical and commercial supply of our product candidates, or the raw material components thereof;
- the costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive regulatory authorization or approval;
- the costs necessary to obtain regulatory authorizations or approvals, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where authorization or 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 and retain 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 costs of operating as a public company; and
- the impact of any business interruptions to our operations or to those of our third-party contractors resulting from any public health crisis.

We may require additional capital to achieve our business objectives. In December 2023, we entered into a Controlled Equity OfferingSM Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co., as sales agent (“Cantor”), pursuant to which we may, at our option, offer and sell up to an aggregate amount of \$75.0 million of our common stock, through Cantor, acting as sales agent. To date, we have sold 9,000,000 shares of our common stock under the Sales Agreement, resulting in net

proceeds of \$39.3 million. Funds additional to the proceeds we may raise under the Sales Agreement 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. If we are unable to secure additional funding when needed, 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 from sales of authorized or approved products, such as PEMGARDA, which received an EUA from the FDA in March 2024, we expect to finance our operations through a combination of equity offerings, government or private-party funding or grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements. 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, including pursuant to our existing Sales Agreement with Cantor, 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 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 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 variants 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 and to obtain and maintain 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, 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, which may significantly and adversely affect our ability to complete our clinical trials and to obtain and maintain authorization or approval of, and commercialize our product candidates. For example, although preclinical 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.

PEMGARDA, which received an EUA from the FDA in March 2024, is an engineered version of adintrevimab, which we modified to improve binding to the Omicron variant and its sublineages. The EUA of PEMGARDA was based on the totality of scientific evidence available, including data showing that the calculated serum neutralizing antibody titers against JN.1 were consistent with the titer levels associated with efficacy in prior clinical trials of adintrevimab, the parent mAb for pemivibart, and other mAbs that were previously authorized for EUA. However, newly emerging and future SARS-CoV-2 variants could reduce the neutralizing activity and effectiveness of PEMGARDA. If this were to occur, the FDA may revise or revoke the EUA for PEMGARDA based on any such reduction in neutralizing activity or effectiveness of PEMGARDA, which would adversely affect our commercial prospects, and our ability to generate revenues from PEMGARDA may be limited or lost.

PEMGARDA is our first mAb in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution. As the SARS-CoV-2 virus evolves over time, we anticipate leveraging our INVYMAB platform approach to periodically introduce new or engineered mAb candidates. We expect that VYD2311, a mAb optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1, will be the next pipeline program to advance into clinical development. 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 of VYD2311. 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 preclinical 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 our planned 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 and maintain authorization or approval of and commercialize VYD2311 or any future product candidates. In addition, if our planned dosing of a product candidate 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. Even if we obtain authorization or approval, such authorization or approval may be revised or revoked based on changes in circulating variants that reduce the neutralizing activity or effectiveness of our product candidates.

To date, we have received regulatory authorization for only one product candidate, PEMGARDA. All of our other product candidates, other than adintrevimab, are currently in preclinical development. If we are unable to successfully develop, receive and maintain an EUA or regulatory approval 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.

To date, we have received regulatory authorization for only one product candidate, PEMGARDA, which has not been approved, but has been authorized for emergency use by the FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg). We currently have no other products approved or authorized for sale, and all of our other product candidates, other than adintrevimab, are currently in preclinical development. Adintrevimab is an investigational mAb that we previously advanced into global Phase 2/3 trials for the prevention and treatment of COVID-19. We 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. Although 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 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. We anticipate that VYD2311, a mAb optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1, will be the next pipeline program to advance into clinical development; however, we cannot be certain of the potential development, regulatory or commercialization timelines of such product candidate. Our ability to generate revenue from our future product candidates 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 PEMGARDA or any other product candidates that we develop or otherwise may acquire will depend on many factors, including:

- the status of new or emerging SARS-CoV-2 variants and whether such SARS-CoV-2 variants reduce the neutralizing activity and effectiveness of PEMGARDA or any other mAb candidates we may develop, and whether we are successful in timely identifying new mAb candidates that mitigate the risk of reduced neutralizing activity and effectiveness against future SARS-CoV-2 variants;
- the continuing need for therapies for the prevention and treatment of COVID-19, including as a result of the development of COVID-19 into an endemic disease or the inability of other available therapies to effectively address COVID-19;
- the timing and progress of our discovery, nonclinical, and clinical development activities;
- the number and scope of nonclinical and clinical programs we decide to pursue;

- our ability to successfully work with the FDA or other regulatory authorities to establish streamlined development pathways that would allow us to fully leverage our INVYMAB platform approach to efficiently introduce new or engineered mAb candidates targeting SARS-CoV-2;
- 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 or other regulatory authorities as to the design or implementation of our clinical trials, including the use of a correlate of protection (surrogate of clinical efficacy) in an immunobridging approach to a pivotal clinical trial;
- the sufficiency of our financial and other resources to complete the necessary nonclinical studies and clinical trials, manufacture the product candidates and complete associated regulatory activities;
- our ability to establish and maintain agreements with third-party manufacturers and suppliers for clinical supply for our clinical trials and commercial manufacturing and successfully develop, obtain regulatory authorization or approval 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;
- timely receipt of authorizations or approvals from applicable regulatory authorities, and the scope and duration of any emergency use authorization received, such as the EUA for PEMGARDA;
- developing and expanding sales, marketing and distribution capabilities and commercializing products, if authorized or approved, whether alone or in collaboration with others;
- our ability to secure and maintain required state licenses for distribution of our products, if authorized or approved, or other distribution disruptions;
- acceptance of the benefits and use of our products, including method of administration, if authorized or approved, by patients, the medical community and third-party payors, for their authorized or 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;
- our ability to obtain and maintain third-party 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 such coverage or 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, and otherwise protecting our rights in our intellectual property portfolio;
- our ability to maintain compliance with regulatory requirements, 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;
- our ability to maintain a continued acceptable safety, tolerability and efficacy profile of products following any authorization or approval; and
- the impact of any business interruptions to our operations or those of third parties with which we work, including as a result of any public health crisis.

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 PEMGARDA or any other product candidates that we develop or otherwise may acquire, which would materially harm our business. If we do not receive authorization or approval for any future product candidates we develop or otherwise may acquire, we may not be able to continue our operations.

Because our product candidates represent novel approaches to the prevention and/or treatment of a relatively new 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 product candidates. 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 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 product candidates for COVID-19 prevention and/or treatment.

As of the date of this report, no mAb has been approved in the U.S. for prevention (pre- or post-exposure) or treatment of COVID-19. Other than the EUA for PEMGARDA issued by the FDA in March 2024, the FDA previously 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 mAb products, casirivimab/imdevimab, bamlanivimab/etesevimab, sotrovimab, and bebtelovimab 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, other than PEMGARDA, are authorized for use in prevention or treatment of COVID-19 in the U.S. due to loss of activity as new variants emerged.

Because the use of engineered mAbs 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. In pursuing, and eventually obtaining, an EUA for PEMGARDA in the U.S., we aligned with the FDA on a primary efficacy analysis for our CANOPY Phase 3 pivotal clinical trial that used a correlate of protection (surrogate of clinical efficacy) in an immunobridging approach comparing data obtained in the CANOPY clinical trial to certain historical data from our previous Phase 2/3 clinical trial of adintrevimab for the prevention of COVID-19 (EVADE). Based on FDA feedback, the use of a correlate of protection in an immunobridging approach to a pivotal EUA-directed clinical trial may be a reasonable approach for a new mAb candidate when clinical trial data from a “prototype” mAb is available and the new mAb candidate satisfies certain criteria. We continue to engage with the FDA with the aim of establishing expedited and replicable pathways for the authorization or approval of new or engineered SARS-CoV-2 mAbs that emerge from our INVYTAB platform approach. We expect that these discussions with the FDA will continue as we advance VYD2311, a mAb developed using our INVYTAB platform approach. However, there can be no assurance of the outcome of these discussions, that VYD2311 or any future product candidates will meet the necessary criteria to leverage the same pathway to a potential EUA as PEMGARDA or 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 clinical trials, or that the design of or data generated in the clinical 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.

In addition, the FDA or other comparable foreign regulatory authorities may take longer than usual to come to a decision on any request for authorization or approval 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 largely upon our ability to rapidly and perpetually develop engineered mAbs that can broadly neutralize SARS-CoV-2, SARS-CoV and additional pre-emergent coronaviruses. We may fail to deliver mAbs that effectively prevent or treat symptomatic COVID-19. Even if we are able to identify and develop such mAbs, we cannot ensure that such product candidates will achieve authorization or approval to safely and effectively prevent or treat symptomatic COVID-19 or other future coronavirus diseases, or achieve commercial success, even if authorized or approved.

If we uncover any previously unknown risks related to our mAbs, or if we experience unanticipated expenses, problems or delays in developing our product candidates, we may be unable to achieve our strategy of leveraging our INVYMAB platform approach to rapidly and perpetually deliver antibody-based therapies that protect vulnerable people from the devastating consequences of circulating viral threats. 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 product candidates. Since our product candidates 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 authorization or 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 mAbs 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 INVYMAB platform approach may not produce durable, broadly neutralizing, effective or safe mAbs in an adequate time period to address a changing virus. If we are unable to timely identify, develop, obtain and maintain authorization or approval for, and commercialize mAbs on a perpetual basis that keeps pace with viral evolution, our business prospects will be significantly harmed.

PEMGARDA is our first mAb in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution. We anticipate leveraging our INVYMAB platform approach to periodically introduce new or engineered mAb candidates. Our INVYMAB platform approach is designed to produce new or engineered mAb candidates that provide 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. If we are unable to timely identify, develop, obtain and maintain authorization or approval for, and commercialize mAbs on a perpetual basis that keeps 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 and maintain required regulatory authorizations or approvals, we will not be able to successfully commercialize our product candidates, and our ability to generate product revenue will be adversely affected.

To date, we have received regulatory authorization for only one product candidate, PEMGARDA, which has not been approved, but has been authorized for emergency use by the FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg). All of our other product candidates, other than adintrevimab, are in 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 authorized or 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 may test and market our product candidates. Before obtaining regulatory authorization to commercialize any of our product candidates, we must demonstrate through complex and expensive preclinical testing and clinical trials certain efficacy and safety requirements of the applicable regulatory agencies. For regulatory approval, we must demonstrate that our product candidates are both safe and effective for use in each target indication, typically requiring lengthy, large, well-controlled clinical studies. 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, authorization or approval policies, regulations or the type and amount of clinical data necessary to gain authorization or 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 or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for authorization or approval. Moreover, results acceptable to support authorization or approval in one jurisdiction may be deemed inadequate by another regulatory authority to support regulatory authorization or approval in that other jurisdiction. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of an authorization or approval, 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-authorization or 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 authorization for emergency use or approval of a 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 authorize or approve 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 authorization or approval for our product candidates, we still need to build and maintain 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 PEMGARDA or any of our future 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 regulatory authorization or 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 regulatory authorization or 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 or other regulatory authorities as to the design or implementation of our clinical trials, including the use of a correlate of protection (surrogate of clinical efficacy) in an immunobridging approach to a pivotal clinical trial;
- 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 or Ethics Committees opinions 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 or Ethics Committees 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 authorizing or 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 or unsuccessful in obtaining authorization or approval for our product candidates;
- obtain authorization or approval for indications or patient populations that are not as broad as intended or desired;
- obtain authorization or approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings (such as for PEMGARDA) 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 authorization or approval of the product or impose restrictions on its distribution after obtaining authorization or approval.

We, the FDA, other regulatory authorities outside the U.S. or an IRB or Ethics Committees 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 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 authorization or 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 authorization or 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 authorization or approval of our product candidates.

There can be no assurance that the public health emergency in the U.S. declared under the FDCA permitting the FDA to authorize drugs and biologics for emergency use during the COVID-19 pandemic 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, if once granted, such as the EUA for PEMGARDA, it is terminated or revoked, 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 or 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 requests, if submitted, for our product candidates.

On March 22, 2024, we received an EUA from the FDA for PEMGARDA. We may seek an EUA for future product candidates 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 from the FDA and it is granted, such as the EUA for PEMGARDA, such EUA will authorize us to market and sell our COVID-19 mAb 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 known and potential benefits of a product outweigh the known and potential risks and if other regulatory criteria are met.

Although we received an EUA from the FDA for PEMGARDA, there is no guarantee that we will apply for an EUA for adintrevimab, VYD2311 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, such as the EUA from the FDA for PEMGARDA, 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. Additionally, 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 pursue licensure of their products under a BLA. Unless streamlined development pathways are established, we may not pursue a BLA for our product candidates for COVID-19 given the evolving 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 February 4, 2020, the Secretary of HHS determined pursuant to his authority under Section 564 of the FDCA that COVID-19 represented a public health emergency with significant potential to affect national security or the health and security of U.S. citizens living abroad. Following this determination, on March 27, 2020, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, subject to the terms of any authorization issued by the FDA. The EUA request for PEMGARDA was issued under this declaration. The Secretary of HHS may terminate this EUA declaration at any time. If the Secretary of HHS 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, such as the EUA for PEMGARDA, there is no guarantee of the duration for which we would be able to maintain it. The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564 of the FDCA, unless the declaration is terminated or authorization revoked sooner.

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, authorization or approval policies, regulations, and the type and amount of clinical data necessary to gain authorization or approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. Other than the EUA for PEMGARDA in the U.S., we have not obtained regulatory authorization or approval for any other product candidate, and it is possible that we may never obtain regulatory authorization or approval for any other product candidates 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 European Commission, or other required regulatory authorization or approval in other countries.

If an existing EUA, such as the EUA for PEMGARDA, or similar authorization from regulatory authorities outside of the U.S. is revised or revoked, we would be unable to sell our product candidate in the near future and instead, we would need to pursue the traditional regulatory approval processes of the FDA or comparable foreign regulatory authorities. Prior to obtaining approval pursuant to a traditional regulatory approval process 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 or foreign regulatory agencies, that such product candidate is safe, pure and effective for its intended uses. Results from preclinical studies and clinical trials can be interpreted in different ways. Even if we believe the preclinical or clinical data for our product candidates are promising, such data may not be sufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional preclinical studies or clinical trials for our product candidates either prior to or after approval, or it may object to elements of our clinical development programs.

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials or with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- we may be unable to collect sufficient data from clinical trials of our product candidates to support the submission and filing of a BLA with the FDA, MAA with the EMA or other submission;
- we may fail bioresearch monitoring, 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 and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay authorization or 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, increase the costs of compliance or restrict our ability to maintain any regulatory authorizations or approvals 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 clinical 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 regulatory authorization or 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 authorization or 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, initial 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, initial 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 interim, top-line, initial or preliminary 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, any 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, initial 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, our 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 to commercialize 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 for obtaining product approval, or meet the clinical or surrogate efficacy and the safety primary endpoints of the pivotal clinical trial(s) for an EUA (in addition to other regulatory requirements) towards obtaining an EUA. 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 or otherwise meet requirements for an EUA. 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.

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 authorized or approved. Some side effects may not be appropriately recognized or managed by the treating medical staff, such as anaphylaxis that has been seen in the class

of mAbs of which ADG20 and PEMGARDA are a part, and toxicities resulting from mAb therapy targeting an exogenous target, as with our product candidates, which can be nonspecific. Anaphylaxis has been observed with PEMGARDA.

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 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 including boxed warnings or warnings and precautions, costly post-marketing studies, and/or a REMS, among other possible requirements. For example, PEMGARDA has been authorized with a boxed warning for anaphylaxis, which could impede our ability to successfully market and commercialize PEMGARDA and our ability to compete successfully against our competitors.

Such findings could further result in regulatory authorities failing to provide authorization or approval for our product candidates or limiting the scope of the authorized or approved indication, if authorized or 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 any 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 authorization or 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 authorizations or approvals of such product, or seek an injunction against its manufacture or distribution;
- regulatory authorities may require additional warnings on the label, such as the boxed warning for PEMGARDA for anaphylaxis;
- 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 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 authorized or approved, and could significantly harm our business, results of operations and prospects.

Lack of awareness or negative public opinion of mAb therapies and increased regulatory scrutiny of mAb 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 mAb therapies for COVID-19 will depend in part on public acceptance of the use of mAb therapies to prevent or treat COVID-19. Any adverse public attitudes about the use of mAb therapies may adversely impact our ability to enroll clinical trials or successfully commercialize any of our mAb therapies that are authorized or approved. 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 that are authorized or 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 authorization or approval of our product candidates, stricter labeling requirements for those product candidates that are authorized or 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 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 severity and difficulty of diagnosing the disease under investigation;
- 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 mAb 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 a public health crisis, such as 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 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 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, our current mission is focused on antibody-based therapies that protect vulnerable people from the consequences of viral threats, beginning with SARS-CoV-2, and we have committed a significant portion of our financial and personnel resources to the manufacturing and commercialization of PEMGARDA, which received an EUA from the FDA in March 2024. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could change, dissipate or stabilize, which could limit or eliminate demand for PEMGARDA or any new or engineered mAb candidates that we anticipate periodically introducing in the future as the SARS-CoV-2 virus evolves over time.

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 have conducted and may in the future conduct 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 have conducted and may in the future conduct clinical trials for our product candidates outside the U.S. The FDA may not accept or may impose additional conditions on trial data from clinical trials conducted outside the U.S. submitted in support of an IND, EUA or BLA. For example, in order for the FDA to accept a foreign clinical trial as support for an IND or application for marketing approval, the FDA requires the following conditions are met: (i) the foreign data are applicable to the U.S. population and U.S. medical practice; (ii) the trial was conducted in accordance with cGCP standards; and (iii) 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 authorization 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 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 public health outbreaks, pandemics or epidemics, such as the COVID-19 pandemic.

COVID-19, the disease caused by SARS-CoV-2 and its variants, gave rise to a global pandemic in 2020, and continues to present public health and economic challenges around the world. The full impact of the COVID-19 pandemic remains uncertain, and such impact may directly or indirectly affect the commercial prospects of our product candidates for the prevention and treatment of COVID-19. The evolution and of the disease and the continued emergence of VoCs, and the availability, administration and acceptance of vaccines, mAbs, antiviral agents and other therapies may 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 public health outbreaks, pandemics or epidemics, such as the COVID-19 pandemic, which pose the risk that we or our third-party contractors may be prevented from conducting normal business activities or operations due to spread of the disease, or due to restrictions that may be requested or mandated by federal, state or local governmental authorities. Business disruptions could include travel restrictions, temporary closures of our facilities or the facilities of our third-party contractors or other restrictions by authorities to reduce the spread of the disease. Any such business disruptions may negatively impact productivity, raise the cost of materials or otherwise disrupt our supply chain or manufacturing activities, and may disrupt our ongoing research and development activities as well as our clinical programs and timelines or commercialization efforts, the magnitude of which will depend, in part, on the length and severity of any such business disruptions, restrictions or other limitations on our ability to conduct our business in the ordinary course.

We experienced some delays in our development activities as a result of the COVID-19 pandemic. For example, 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. There could be other disruptions, delays or uncertainties in our development activities as a result of any public health outbreak, pandemic or epidemic, such as the COVID-19 pandemic.

Public health outbreaks, pandemics or epidemics, such as the COVID-19 pandemic, which caused a broad impact globally, may also materially affect us economically. For example, a widespread outbreak, pandemic or epidemic 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 disease such as COVID-19 could materially affect our business and the value of our common stock. The ultimate extent to which COVID-19 directly or indirectly impacts 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 VoCs, actions taken to prevent or treat COVID-19, and its economic impact on local, regional, national and international markets.

In addition, to the extent that any public health outbreaks, pandemics or epidemics, such as 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 product candidates for use in combination with other therapies or third-party product candidates, which exposes us to additional regulatory risks.

We may develop 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 authorization or approval to be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA or comparable foreign regulatory authorities could revoke authorization or 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.

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

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

Authorized and 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-authorization or 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 authorization or approval altogether.

The United Kingdom’s withdrawal from the European Union may adversely impact our ability to obtain regulatory authorizations or 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 potential 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 continues to be covered by the marketing authorizations granted by the European Commission, but this will change beginning on January 1, 2025, when the new measures under the Windsor Framework come into effect. Beginning on this date, Northern Ireland will be subject to the same MHRA authorization procedures as Great Britain.

All of these changes could increase our costs and otherwise adversely affect our business to the extent that we pursue development, manufacture, and/or commercialization of our product candidates in the European Union or United Kingdom. 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. 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, extend 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 face significant additional expenses (when compared to prior to the end of the Transition Period) to operate our business, to the extent that we pursue development, manufacture, and/or commercialization of our product candidates in the European Union and United Kingdom, 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.

Risks Related to the Manufacturing of our Product Candidates

Monoclonal antibody therapies are complex and difficult to manufacture, and we currently rely on a contract manufacturer 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 mAb 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.

We have engaged WuXi Biologics, a CDMO, for the development and manufacture of our product candidates for clinical and commercial use. 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 CDMO 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 or foreign or state regulatory authorities. If we or our CDMO were to fail to comply with the FDA or 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 authorizations or 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 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 authorization or 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 or to have enough manufacturing slots to manufacture our product candidates to meet clinical or commercial requirements and demands;
- unfavorable FDA or 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 third-party contractors 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 commercialization could be delayed or stopped.

All entities involved in the preparation of therapeutics for clinical trials or commercialization, including our existing contract manufacturer and testing facilities, labeling, packaging and storage facilities, and distributors, are subject to extensive regulation. Components of a finished therapeutic product authorized or approved for commercialization 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 authorized or 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 manufacturer must supply all necessary documentation in support of regulatory authorization or approval on a timely basis. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party contractors will likely need to pass a pre-approval inspection (and may need to pass a pre-authorization inspection) for compliance with the applicable regulations as a condition of regulatory approval (or authorization) of our product candidates. In addition, 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 regulatory authorization or approval) if the facilities or quality systems of our or third-party contractors do not pass such audit or inspections. Certain of our third-party contractors' facilities have not yet been inspected by regulatory authorities. If any of our third-party contractors' facilities do not pass a pre-approval, pre-authorization, or other facility inspection, regulatory approval or authorization of the products may not be granted.

The regulatory authorities also may, at any time following authorization or approval of a product for sale, inspect or audit us or 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 third-party contractors fail to maintain regulatory compliance, the FDA or other regulatory authorities can impose regulatory sanctions, including, among other things, refusal to authorize or approve a pending application or to issue a positive opinion for a new drug product, or revocation of a pre-existing authorization or approval. As a result, our business, financial condition and results of operations may be harmed. Additionally, if supply from an approved manufacturer is interrupted, there could be a significant disruption in commercial supply of any authorized or approved products. An alternative manufacturer would need to be qualified and approved, 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 authorized or approved, or could delay commercial supply once authorized or approved. Furthermore, if our third-party contractors fail to meet contractual requirements, and we are unable to secure one or more replacement contractors capable of production at a substantially equivalent cost, our clinical trials or commercialization efforts may be delayed or we could lose potential revenue.

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

Manufacturing and testing our product candidates and commercialization of PEMGARDA or any other authorized or approved products 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, our current CDMO, as the procurer of the raw materials used in the manufacture of our product candidates, such as PEMGARDA, including certain single-source purification resins and cell culture media, which increases the risk of delays in production.

Our current CDMO's or potential future CDMOs' 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, our current CDMO or potential future CDMOs may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we, our current CDMO or potential 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, our current CDMO or potential future CDMOs rely on and may in the future rely on sole-source suppliers or a limited number of suppliers. 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 could result in delay, and we may not be able to find other acceptable suppliers on acceptable terms, or at all. Switching our suppliers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If our key suppliers 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.

In addition, to date, we have relied on WuXi Biologics as our only CDMO. We have partnered with WuXi Biologics for CMC development and for clinical and commercial drug substance and drug product supply. The loss of this CDMO, a disruption in production at this CDMO or the inability of this CDMO to timely manufacture sufficient quantities to meet our needs, and our failure to find alternative manufacturing capability in a timely fashion, would impair our ability to develop and commercialize our product candidates, including the manufacture and commercialization of PEMGARDA in quantities and on timelines sufficient to meet demand. Although we believe there are other potential alternative CDMOs, the number of CDMOs with the necessary manufacturing and regulatory expertise and facilities to manufacture biologics like our mAb candidates is limited, and switching manufacturers or manufacturing sites would be expensive, difficult and time consuming. A new manufacturer or manufacturing site would have to be educated on, or develop substantially equivalent processes for, production of our product candidates, and it may be difficult or impossible to transfer certain elements of our manufacturing process to a

new manufacturer or for us to find a replacement manufacturer on acceptable terms quickly, or at all. Furthermore, switching manufacturers or manufacturing sites may hinder our ability to leverage our INVYMAB platform approach to facilitate the rapid, serial generation of mAbs to keep pace with evolving viral threats, which we expect will require a consistent CMC platform. Transferring manufacturing to a new manufacturer or manufacturing site could therefore interrupt supply, delay our clinical trials and commercialization efforts, increase our costs for our product candidates and disrupt our plans to use any potential streamlined development pathway that requires a consistent CMC platform, any of which could have an adverse effect on our business, financial condition, results of operations, and/or growth prospects.

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

Given the nature of mAb 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

If the FDA revokes or terminates our EUA for PEMGARDA, we will be required to stop commercial distribution of PEMGARDA immediately unless we can obtain FDA approval for PEMGARDA under a traditional regulatory pathway, which is lengthy and expensive, which could harm our future business prospects.

Under the FDCA, the FDA has authority to allow certain 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 when there are no adequate, approved, and available alternatives. In issuing an EUA, the FDA will consider the totality of scientific evidence available to the FDA regarding safety, efficacy, and known and potential risks of such products and availability of alternatives to the emergency use products, among others. EUAs issued by the FDA specify the scope of authorization and conditions of authorization, including limitations on distribution and conditions related to product advertising and promotion. Once granted, an EUA is effective until the declaration permitting emergency use authorization is terminated or the EUA is revoked, after which the product must be approved by the FDA under a traditional pathway in order to remain on the market or to continue commercialization of the product.

On March 22, 2024, we received an EUA from the FDA for PEMGARDA for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2.

The distribution and advertising conditions set forth in our EUA limit our market opportunities and restrict how we can commercialize PEMGARDA. For example, according to our EUA, among other requirements, all descriptive printed matter, advertising, and promotional materials relating to the emergency use of PEMGARDA under the EUA must be consistent with the authorized labeling and other terms set forth in the EUA and such materials must be tailored to the intended audience, not take the form of reminder advertisements or reminder labeling, and be accompanied by authorized labeling under certain circumstances. In addition, according to our EUA, printed matter, advertising, and promotional materials relating to the emergency use of PEMGARDA must provide accurate descriptions of safety results and efficacy results on a clinical

endpoint(s) or surrogate endpoint(s) from the clinical trial(s) summarized in the authorized labeling, including any limitations of the clinical trial data as described in the authorized labeling, and contain certain clear and conspicuous statements regarding the emergency use authorization. In addition, the PEMGARDA Fact Sheet for Healthcare Providers includes a boxed warning for anaphylaxis. If the FDA's policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of PEMGARDA could be adversely impacted.

In addition, the FDA would be required to revoke our existing or any future EUA if HHS determines that emergency use is no longer warranted. The FDA may also revoke our existing or any future EUA if new evidence becomes available that indicates that PEMGARDA is not as safe, effective, or reliable as the data provided in the EUA request. For example, the FDA may revise or revoke the EUA for PEMGARDA based on changes in circulating SARS-CoV-2 variants and a reduction in neutralizing activity or effectiveness of PEMGARDA against such variants. We cannot predict how long our EUA will remain effective, and we may not receive advance notice from the FDA regarding revocation of our EUA. The termination or revocation of our existing EUA for PEMGARDA would cause us to cease our commercialization efforts until and if we have obtained approval from the FDA through another regulatory pathway and would adversely impact our business, financial condition and results of operations.

Additionally, changes in FDA policies, guidance, and requirements for the submission of an EUA request may delay authorization of any additional emergency uses for PEMGARDA. Further, given the high volume of EUA requests received by the FDA and other factors due to the COVID-19 pandemic, including any disruptions in the FDA's normal operations, the FDA's review of an amended or additional EUA request may be significantly delayed. The FDA may not grant an EUA for additional emergency uses of PEMGARDA on a timely basis or at all, which could harm our future business prospects.

Even if any of our product candidates receive authorization or approval, such as PEMGARDA, 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, due to the product profile, reimbursement dynamics or other reasons.

If any of our product candidates receive authorization or approval, such as PEMGARDA, which received an EUA from the FDA in March 2024, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community, due to the product profile, reimbursement dynamics or other reasons. 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 authorized or approved for sale, including PEMGARDA, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments, including oral, intramuscular (IM) and intravenous (IV) 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 or other foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, including any boxed warning (such as the boxed warning for anaphylaxis for PEMGARDA) or REMS;
- whether we are required by the FDA or other regulatory authorities to conduct additional clinical trials or to modify the design of our current trials to support the initial or continued authorization or approval of a product candidate;
- 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, such as anaphylaxis for which PEMGARDA received a boxed warning;
- 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.

Even though we have received an EUA for PEMGARDA, it may not gain broad market acceptance among physicians, healthcare payors and others in the medical community. The commercial success of PEMGARDA is dependent upon physicians, healthcare providers and patients adopting PEMGARDA, which will be informed, in part, by the cost, convenience, safety and efficacy of PEMGARDA. The efficacy of PEMGARDA could be negatively impacted by novel strains of SARS-CoV-2 with genetic variations from viral mutation over time.

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

We will need to build and maintain a commercial infrastructure to support the anticipated marketing and distribution of our product candidates, which we will need to achieve commercial success for PEMGARDA and any other product candidate for which we may obtain authorization or marketing approval. To support the commercialization of PEMGARDA, we have directly hired key leaders for our sales, marketing, market access, and medical affairs teams, and we are leveraging contract organizations for certain field-based roles. There are risks involved with establishing our commercial infrastructure. For example, the establishment of our own commercial team and/or the hiring and training of a contract sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we develop a commercial team and/or hire a contract sales force to 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 develop and maintain our commercialization capabilities include:

- our inability or the inability of a contract organization 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.

To the extent that we rely on third parties to perform sales, marketing or distribution services, such as our leveraging of contract organizations for certain field-based roles for the commercialization of PEMGARDA, our revenue and our profitability, if any, are likely to be lower than if we had developed such capabilities ourselves. In addition, 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.

We began commercializing PEMGARDA after we received an EUA from the FDA in March 2024. As a result, we have only limited experience marketing our product candidates. Our financial condition and results of operations are and will continue to be highly dependent on the ability of our marketing function to adequately promote PEMGARDA for appropriate patients in a manner that complies with applicable laws and regulations.

A key element of our business strategy is the continued expansion of our marketing infrastructure and building brand awareness. As we increase our marketing efforts in connection with the expansion of PEMGARDA sales, we will need to further expand the reach of our marketing networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate a skilled marketing workforce, directly or through contract organizations, with significant industry-specific knowledge in various areas, including healthcare, prophylactic treatments, complex biologics, and applicable laws and regulations.

If we are unable to expand our marketing capabilities, we may not be able to effectively commercialize PEMGARDA. Relatedly, if any of our marketing platforms significantly increase their advertising fees, our ability to expand our marketing reach will be greatly impeded. Any such failure could adversely affect our reputation, revenue, and results of operations.

The affected populations for our product candidates, including PEMGARDA, 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. In considering the market potential for our product candidates, our projections of the number of immunocompromised people in the U.S. who may not adequately respond to COVID-19 vaccination and the estimated U.S. total addressable market for our mAb candidates for the pre-exposure prophylaxis of COVID-19 are estimates based on

Inviyd-sponsored market research and our internal analysis. The number of immunocompromised people in the U.S. who may not adequately respond to COVID-19 vaccination and the estimated U.S. total addressable market for our mAb candidates for the pre-exposure prophylaxis of COVID-19 may turn out to be lower than expected, and patients may not be amenable to 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 COVID-19, 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 targeting 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, the number of patients that we will be able to successfully treat with our product candidates, if authorized or approved, such as PEMGARDA, will be decreased.

The total addressable market opportunity for our product candidates, including PEMGARDA, will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included on the final label, if authorized or 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 has involved using a third party to model the number of people at high risk for severe COVID-19 based on a combination of different data sets, such as the incidence and prevalence of different medical conditions based on primary literature, the portion of patients who are receiving immunosuppressants based on claims data, and interviews/surveys with health care professionals. 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 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 may in the future obtain an EUA or similar authorization or obtain regulatory approval and have commercial rights) and our ability to meet the market demand. If the markets or patient subsets that we are targeting are not as significant as we estimate, or if we do not have sufficient supply to meet the market demand, we may not generate significant revenues from sales of such products, even if authorized or 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 authorized or approved by the FDA or 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 or 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 authorization or 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 products in the European Union is subject to European Union Member States’ national laws implementing Titles VIII and VIIIa of Directive 2001/83/EC on the Community code relating to medicinal products for human use, 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 medicinal products. European Union Member States’ legislation may also restrict or impose

limitations on the ability to advertise products directly to the general public. In addition, voluntary European Union and national Codes of Conduct provide guidelines on the advertising and promotion of products to the general public and may impose limitations on 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.

Our mAb product candidates may face significant competition from vaccines, antiviral agents and other therapeutics, including mAbs, 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 with a perceived superior risk-benefit profile or other perceived superior attributes such as mode of administration or dosing regimen, develops a therapeutic at a lower cost or is more successful at commercializing an approved therapeutic, we may not be able to successfully commercialize PEMGARDA or any other product candidate targeting COVID-19, even if authorized or approved, or compete with other therapeutics or vaccines, which could adversely impact our business and operations. For example, PEMGARDA has been authorized with a boxed warning for anaphylaxis, which could impede our ability to successfully market and commercialize PEMGARDA and our ability to compete successfully against our competitors.

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 authorizations or 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 mAbs and other biological products, that have been authorized or 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 authorized or approved in the future for the prevention or 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 and maintain required regulatory authorizations or approvals;
- obtain placement in COVID-19 prevention and treatment guidelines from organizations such as the CDC, the WHO and the Infectious Diseases Society of America (the “IDSA”);
- obtain coverage and adequate reimbursement from, and negotiate competitive pricing with, third-party payors;
- manufacture sufficient supply to meet market demand; 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, including PEMGARDA. 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 mAbs by other companies could impact the anticipated reimbursement structure of our mAbs, if authorized or approved, and our business, financial condition, results of operations and prospects.

Additionally, government entities, such as the CDC, the WHO and non-government professional societies, such as the IDSA, may produce treatment and/or prevention guidelines for COVID-19, including the use of mAbs for these indications. However, our mAbs, 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 authorized or 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 authorization or approval for, or commercializing, drugs before we do, which would have an adverse impact on our business and results of operations.

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 PEMGARDA, 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. In the U.S., the principal decisions about Medicare 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. CMS has published in the Calendar Year Physician Fee Schedule a final rule that all COVID-19 mAbs for pre-exposure prophylaxis of COVID-19 and their administration will be covered and reimbursed under the Part B preventative vaccine benefit. CMS has not communicated a timeline for publishing this information following the granting of any EUAs by the FDA for such products. A significant delay in publication of product specific billing codes and their payment rates could impact initial prescription rates by providers and patients.

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. 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 product 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, may produce treatment and/or prevention guidelines for the prevention and treatment of COVID-19, including guidance regarding the use of mAbs in these indications. If our product candidates, to the extent authorized or approved, fail 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 any such 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 authorized or 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 authorizations or 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, to the extent any of our product candidates are authorized or approved outside of the U.S. For example, 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 products in some European countries, including some European Union member states, data comparing the cost-effectiveness of products to other available therapies may be required. 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 in the future we seek but are unable to obtain and then maintain favorable pricing and reimbursement status in European Union member states that represent significant markets, our anticipated revenue from and growth prospects for products in the European Union could be negatively affected. If we experience setbacks or unforeseen difficulties in obtaining favorable pricing and reimbursement decisions, any planned launches in the affected European Union member states would be delayed, which could negatively impact any anticipated revenue from and growth prospects for relevant product candidates.

There can be no assurance that PEMGARDA or any other product candidate, if authorized or 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 authorized or approved for sale.

Any product candidates for which we determine to seek approval as biological 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 biological 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 biological 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 as we sell any products that have been authorized or approved, such as PEMGARDA, which received an EUA from the FDA in March 2024. 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. For example, in the CANOPY clinical trial, the most common adverse events (all grades, incidence $\geq 2\%$) observed in participants who have moderate-to-severe immune compromise treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea. Anaphylaxis has been observed with PEMGARDA, and the PEMGARDA Fact Sheet for Healthcare Providers includes a boxed warning for anaphylaxis. 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 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', 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 our CDMO, 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 rely on third parties to manufacture, package and label 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 CDMO, 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.

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 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” (i.e., certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function 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.

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. The GDPR imposes substantial fines for breaches and violations (for the most serious breaches of up to the greater of €20 million or 4% of 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. In addition, the GDPR increases the scrutiny of transfers of personal data from the EEA, including the European Union, United Kingdom and Switzerland, to other jurisdictions that the European Commission/United Kingdom Secretary of State, as applicable, does not recognize as having “adequate” data protection laws. While, previously, United States companies could rely on self-certification to the EU-U.S. and Swiss-U.S. Privacy Shield frameworks administered by the United States Department of Commerce as one of these safeguards to legitimize transfers from the European Union and Switzerland to the United States, this has been invalidated by the Court of Justice of the European Union (the “CJEU”). The CJEU found that the Standard Contractual Clauses (“SCCs”), one of the primary safeguards for legitimizing data transfers, were valid in principle, but placed obligations on the parties entering into them including to verify whether an adequate level of protection is provided in the recipient jurisdiction, and whether additional measures are required to bring the level of protection in line with European Union standards. Following this decision, the European Data Protection Board issued guidance on how organizations should approach international data transfers of GDPR-covered personal data, including the supplemental measures companies can adopt to help protect against overarching surveillance outside of the European Union. In June 2021, the European Commission adopted a new set of SCCs aimed at enabling lawful transfers of personal data to non-adequate countries outside the EEA, the deadline for the adoption of which was December 27, 2022. There are also recent developments regarding data transfers in the United Kingdom, which formally approved two mechanisms for transferring United Kingdom-data overseas and that came into effect on March 21, 2022. The United Kingdom Information Commissioner’s Office also issued guidance on how to approach undertaking risk assessments for transfers of United Kingdom- data to non-adequate countries outside the United Kingdom. With respect to the United States, on July 10, 2023, the European Commission adopted its adequacy decision for the EU-US Data Privacy Framework, providing for personal data to flow freely from the European Union to United States-based companies that participate in the Data Privacy Framework. The adequacy decision followed the adoption by United States President Biden of an executive order as well as regulation issued by the United States Attorney General.

A lack of valid transfer mechanisms for GDPR-covered data could increase exposure to enforcement actions as described above and may affect our business operations and require commercial cost (including potentially limiting our ability

to collaborate/work with certain third parties and/or requiring an increase in our data processing capabilities in the European Union and United Kingdom). Further, the European Union and United Kingdom data protection laws (including laws on data transfers as set out above) may also be updated/revise, accompanied by new guidance and/or judicial/regulatory interpretations, which could entail further impacts on our compliance efforts and increased cost.

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 California Consumer Privacy Act (“CCPA”) took effect on January 1, 2020 and was later amended by the California Privacy Rights Act (“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 continues to draft and propose 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 of certain types of data 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, went into effect during 2023 and have potentially conflicting requirements that would make compliance challenging and present legal risk. Other states, such as Indiana, Iowa, Montana, and Texas have implemented similar laws which 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.

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, package, 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 or authorization 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, store and distribute clinical and commercial supplies of our product candidates.

We are currently manufacturing, testing, labeling, packaging, storing and distributing our product candidates in partnership with third-party contractors. We do not own or operate any facilities for product manufacturing, testing, labeling, packaging, or storage. We are dependent on third parties to manufacture, test, 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 as our CDMO to manufacture our product candidates for clinical and commercial supply.

The facilities used by our third-party contractors to manufacture and test our product candidates may be inspected by the FDA after we submit an EUA or a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our CDMO for compliance with the cGMP requirements. If our CDMO 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 authorization or approval for our product candidates. In addition, we have limited control over the ability of our CDMO 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 timely develop, obtain regulatory authorization or approval for or market our product candidates, if authorized or approved. If we are not able to meet market demand for any authorized or 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 have engaged WuXi Biologics for development and generation of the production cell line starting material manufacturing for our product candidates. 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. 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 or supply 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. Foreign CDMOs may also be the subject of U.S. legislation. For example, in late-2023 and early-2024, there was congressional activity, including the introduction of the BIOSECURE Act (H.R. 7085) in the House of Representatives and a substantially similar Senate bill (S.3558), which discourage contracting with Chinese biotechnology companies, and specifically WuXi Apptec and its subsidiaries on the development or manufacturing of pharmaceutical products. If this legislation became law, or if a similar law were passed, it would have the potential to severely restrict the ability of U.S. biopharmaceutical companies like us to purchase services or products from, or otherwise collaborate with, certain Chinese biotechnology companies "of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. It is possible some of our contractual counterparties, including WuXi Biologics, could be impacted by the legislation described above. If WuXi Biologics or any of the other third parties that we engage to supply any materials or manufacture products for our preclinical tests and clinical trials should cease to continue to do so for any reason, we could experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us, or at all. In addition, if we are not able to

obtain adequate supplies of our products or product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates, commercialize our products and compete effectively.

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 on desired timelines;
- inability of a third-party manufacturer 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 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 a third-party manufacturer 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 a third-party manufacturer 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 or maintain regulatory authorization or approval or impact our ability to successfully commercialize our product candidates, if authorized 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, under which Adimab has assigned to us its rights, title and interest in and to certain of its coronavirus-specific antibodies, including modified or derivative forms thereof, and related intellectual property. Pursuant to the Adimab Assignment Agreement, Adimab additionally granted us 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 for all indications and uses, with the exception of certain diagnostic uses and use as a research reagent. Under the Adimab Assignment Agreement, we are obligated to use commercially reasonable efforts to achieve specified development and regulatory milestones for subject products in certain major markets and to commercialize a subject 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 any subject products, in accordance with the Adimab Assignment Agreement, beginning upon the first commercial sale of a subject product in accordance with the Adimab Assignment Agreement, on a product-by-product and country-by-country basis, for a period 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.

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 could 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 our exercise of an option, 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. The Adimab Collaboration 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 subject products, in accordance with the Adimab Collaboration Agreement, on a product-by-product and country-by-country basis, for a period 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 claiming composition of matter or method of making or using any antibody identified or optimized under the Adimab Collaboration Agreement in such country.

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 has been 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 allows 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. After such time, until 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. The Adimab Platform Transfer 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 net sales of subject products, in accordance with the Adimab Platform Transfer Agreement, on a product-by-product and country-by-country basis, for a period 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 program antibody patent for covering the program antibody contained in such product in such country.

While we are building our internal capabilities in order to discover and develop mAb candidates, our business continues to be 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 foregoing, 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.

As one example, in Europe, a new unitary patent system became effective in June 2023, which may significantly impact European patents, including those granted before the introduction of such a system. Under the unitary patent system, European applications will soon have the option, upon grant of a patent, of becoming a Unitary Patent which will be subject to the jurisdiction of the Unitary Patent Court (“UPC”). As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation. Patents granted before the implementation of the UPC will have the option of opting out of the jurisdiction of the UPC and remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC will be potentially vulnerable to a single UPC-based revocation challenge that, if successful, could invalidate the patent in all countries who are signatories to the UPC. We cannot predict with certainty the long-term effects of any potential changes.

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 product 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 our 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. In October 2023, Ipsen Biopharm, LTD and its affiliates filed oppositions against our trademark applications for INVIVYD in the USPTO based on Ipsen's registered trademark for the oncology drug ONIVYDE. Prior to that, in July 2023, Ipsen and its licensee Les Laboratoires Servier filed oppositions against our trademark applications for INVIVYD in Switzerland, United Kingdom, European Union, and Australia, likewise based on ONIVYDE. As of November 1, 2023, action has been suspended in all proceedings to allow for settlement negotiations. The outcome of these settlement negotiations or, in the alternative, the opposition proceedings, is uncertain.

If we are found to infringe the trademark rights of Ipsen, its licensee, or another third party, 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. In the event such infringement is found to have caused commercial harm, 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 trademark at issue. 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

We received an EUA for PEMGARDA, which the FDA would be required to revoke if HHS determines that emergency use is no longer warranted, which would adversely impact our ability to market PEMGARDA in the United States.

The FDA has the authority to grant an EUA to allow unapproved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions when there are no adequate, approved and available alternatives. On March 22, 2024, we received an EUA from the FDA for PEMGARDA for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2.

The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the FDCA, unless the declaration is terminated or authorization revoked sooner. Because the FDA is required to revoke an EUA if HHS determines that emergency use is no longer warranted, we cannot predict how long our EUA for PEMGARDA will remain in place. If the FDA terminates or revokes our EUA for PEMGARDA prior to us having pursued and received regulatory approval to commercialize PEMGARDA through a traditional approval pathway, we would be required to cease our commercialization efforts, which would substantially and negatively impact our business.

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 False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment of government funds, including from 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 investigated and have reached substantial financial settlements with the federal government under the civil False Claims Act for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. The government may deem companies to have “caused” the submission of false or fraudulent claims by, for example, 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 our product candidates, such as PEMGARDA, which received an EUA from the FDA in March 2024, 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. For example, we will be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our authorized or approved products to regulatory authorities along with other periodic reports. 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. Additionally, the FDA has expected that companies that receive an EUA for COVID-19 antibodies will proceed to licensure of their products under a BLA, which, if required of us by the FDA with respect to any product candidate for which we receive an EUA, would be time-consuming and expensive.

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, such as PEMGARDA. 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 authorization or approval, commonly known as off-label promotion. If one or more of our products were granted an EUA, such as PEMGARDA, there are additional limitations the FDA places upon manufacturers as to promotional communications and 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, including our EUA for PEMGARDA, 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 an EUA, 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 records related to safety reporting. The EMA's Pharmacovigilance Risk Assessment Committee may propose to the Committee for Medicinal Products for Human Use that a 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 authorization or 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 authorization or 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 successfully commercialize PEMGARDA or any future product candidates and harm our business, financial condition, results of operations and prospects.

Despite obtaining authorization under an EUA for PEMGARDA in the U.S., we may never obtain authorization or approval for or commercialize PEMGARDA or any other product candidate 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 PEMGARDA or any other product candidates, if authorized or approved, we will need to secure and maintain required state licenses.

Authorization or approval by the FDA in the U.S. 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.

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 other than PEMGARDA in the U.S. under an EUA, 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 market opportunity 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 regulatory authorization or approval of product candidates, restrict or regulate post-authorization or post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain regulatory authorization or 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. The ACA 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 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 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 the ACA-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and 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, sequestration is currently set at 2% through the first 7 months of 2032. 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, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, effective 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. The Inflation Reduction Act of 2022 (the “IRA”), among other things, 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. 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. Failure to comply with requirements under the Part D benefit redesign is subject to a civil monetary penalty. The IRA also prohibits Medicare Part D plans from imposing cost-sharing for certain vaccines that are recommended by the Advisory Committee on Immunization Practices.

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 will be 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 our 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 authorization or approval;
- changes to manufacturing methods;
- recalls, replacements or discontinuance of one or more of our products, if authorized or approved; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs, or could reduce the potential commercial value of our product candidates, and could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory authorizations or approvals for our 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, scientific, clinical, manufacturing, commercial, financial, legal 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, clinical, manufacturing, and commercialization personnel, including market access, marketing and sales personnel, are also critical to our success. The loss of the services of our executive officers or other

key employees could impede the achievement of our development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory 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 and executing 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. We also rely on contractors to support the sales, market access and medical affairs activities for commercialization and scientific exchange. If we are unable to continue to attract and retain high quality personnel and engage high quality contractors, our ability to pursue our growth strategy and achieve our business objectives 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 19.7% of the voting power of our outstanding common stock according to a Schedule 13D Amendment filed by Adimab on January 22, 2024, which reported ownership as of January 19, 2024. 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.

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 have implemented 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 progress, 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 sales, marketing and distribution. To manage our future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit, train and retain 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, train and retain such 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, CDMO, 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, CDMO, 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 12, 2024, our common stock has traded at prices ranging from \$0.98 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 commercial performance of PEMGARDA;
- our ability to leverage our INVYMAB platform approach to timely identify, develop, obtain authorization or approval for, and commercialize mAbs on a perpetual basis that keeps pace with viral evolution;
- 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;
- the timing of our regulatory filings for our product candidates, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's receipt and review of such filings, including without limitation the FDA's declination to accept or review an EUA application submission or an issuance of a "refusal to file" letter or a request for additional information;
- our ability to maintain our EUA for PEMGARDA, and the receipt of any additional or amended EUAs from the FDA for PEMGARDA and the timing thereof;
- delays in or termination of clinical trials;
- adverse regulatory decisions, including failure to receive regulatory authorization or approval of our product candidates;
- serious safety concerns related to the use of PEMGARDA 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, as amended, 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, as amended, 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 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 relatively new 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.

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. On February 9, 2024, we filed a registration statement on Form S-3 to register an aggregate of up to 37,745,998 shares of our common stock held by holders with registration rights, including 30,921,286 issued and outstanding shares of our common stock and 6,824,712 shares of common stock issuable upon exercise of an outstanding common stock purchase warrant issued by us. Once such Form S-3 is declared effective by the SEC, such shares of common stock may be freely sold in the public market for so long as such Form S-3 remains effective, subject to the vesting and the exercise of the common stock purchase warrant with respect to the shares of common stock underlying such warrant. 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:

- 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:

- 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 so long as either of the following conditions are true – (i) the market value of our common stock held by non-affiliates is less than \$250 million as of the end of that year’s second fiscal quarter, or (ii) our annual revenues are less than \$100 million

during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than \$700 million as of the 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, as applicable, including the net proceeds from our IPO and any sales of our common stock made under our Sales Agreement with Cantor.

We have broad discretion over the use of our cash, cash equivalents and marketable securities, as applicable, including the net proceeds from our IPO and any sales of our common stock made under Sales Agreement with Cantor. 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, we have incurred and, particularly after we are no longer an emerging growth company, 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. This lawsuit, 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 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, as amended, 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, as amended, 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. By letter dated August 9, 2023, the SEC notified us that the SEC had concluded its investigation and did not intend to recommend any action against us.

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, 2023, we had U.S. federal net operating loss ("NOL") carryforwards of \$318.6 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, 2023, we had state NOL carryforwards of \$153.8 million, which may be available to reduce future taxable income, of which \$9.6 million have an indefinite carryforward period while the remaining \$144.2 million begin to expire in 2032. As of December 31, 2023, we also had U.S. federal and state research and development tax credit carryforwards of \$19.3 million and \$6.4 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.

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.

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, manufacturer, 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 manufacturer, 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.

If a prolonged government shutdown occurs, or if global health concerns 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, including as a result of trade tensions between the U.S. and China. Sanctions imposed by the U.S. and other countries in response to 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. We have conducted and may in the future conduct clinical trials for our product candidates 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 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 authorized or 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 or changes in U.S. trade policies, particularly with China, could also strain our manufacturer 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 1C. Cybersecurity.

Risk Management and Strategy

We have established policies and processes for assessing, identifying, and managing the risks from foreseeable cybersecurity threats and for detecting and responding to any cybersecurity incidents. These policies and processes are built into our information technology (“IT”) function and are designed to align with the NIST Cybersecurity Framework, published by the U.S. National Institute of Standards and Technology.

We have adopted an IT Security Management Policy (“IT Policy”) to establish the requirements for securing and managing our IT assets and data, as well as an Incident Response Policy designed to coordinate the activities for preparing for, identifying, responding to, and recovering from cybersecurity threats. Our Head of IT is primarily responsible for implementing and overseeing the IT Policy, which is applicable to all our employees and contractors, as well as any third parties with access to our IT assets and data. Our Head of IT is also primarily responsible for leading incident response services under the Incident Response Policy. Our Head of IT leverages over 20 years of experience in various cybersecurity functions. As part of our overall risk mitigation strategy, we maintain an Enterprise Risk Register to identify, prioritize and track system risks, including cybersecurity risks. Additionally, we maintain cybersecurity insurance; however, such insurance may not be sufficient in type or amount to cover the total losses or damages related to a cybersecurity incident.

We implement technical, physical, and organizational measures designed to manage and mitigate risks from cybersecurity threats. For example, we employ multifactor authentication, single sign-on, and email filtering services across our systems. Additionally, we conduct monthly video-based cybersecurity awareness trainings across our workforce, which cover relevant topics such as social engineering, phishing, password protection, confidential data protection, and mobile security. We regularly perform company-wide phishing tests. We currently leverage multiple third-party service providers to assist in monitoring, managing, and detecting cybersecurity threats and conducting periodic vulnerability assessments of our critical assets.

As of the date of this report, we are not aware of any cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition. However, evolving cybersecurity threats make it increasingly challenging to anticipate, detect, and defend against cybersecurity threats and incidents.

Governance

While our Board of Directors has overall responsibility for risk oversight, the Audit Committee of our Board of Directors (the “Audit Committee”) is responsible for overseeing our cybersecurity risk management and strategy. The Audit Committee reviews and discusses with management and the Company’s auditors, as appropriate, our risks relating to data privacy, technology, and information security, including cybersecurity and back-up of information systems. The Audit Committee also confers with management and our auditors, as appropriate, regarding the adequacy and effectiveness of our policies and the internal controls regarding information security.

Our Head of IT meets regularly with our Chief Operating Officer to discuss our cybersecurity threat landscape, address open gaps and issues, and evaluate solutions to cover any identified gaps. Our Head of IT, in collaboration with members of senior management, reports relevant cybersecurity matters to our Audit Committee.

For discussion of cybersecurity risks, please see Item 1A, “Risk Factors.”

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. The court appointed lead plaintiffs for the action on June 28, 2023. On August 23, 2023, the lead plaintiffs filed an amended complaint that makes allegations similar to those in the original complaint and asserts the same claims against the same defendants as the original complaint. On October 19, 2023, the parties filed a joint stipulation to advise the court that the lead plaintiffs intended to seek leave to file a second amended complaint, and on November 22, 2023, the lead plaintiffs filed a second amended complaint that makes allegations similar to those in the prior complaints and asserts the same claims against the same defendants as the prior complaints. On January 12, 2024, the defendants filed a motion to dismiss the second amended complaint in its entirety. The lead plaintiffs filed an opposition to the motion to dismiss on February 26, 2024, and the defendants filed a reply in further support of their motion to dismiss on March 27, 2024.

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.

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 12, 2024, there were 11 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, 2023.

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

Period	Total Number of Shares (or Units) Purchased	Average Price Paid per Share (or Unit)	Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 1, 2023 to October 31, 2023	31,765	⁽¹⁾ \$ 0.002	—	—
November 1, 2023 to November 30, 2023	—	—	—	—
December 1, 2023 to December 31, 2023	—	—	—	—
Total	<u>31,765</u>	<u>\$ 0.002</u>	<u>—</u>	<u>—</u>

⁽¹⁾ We repurchased shares of our common stock that were previously issued upon the early exercise of employee stock options in connection with the exercise of our repurchase right upon cessation of service of certain of our employees and directors.

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

Inviydy, Inc. is a commercial-stage 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. INVYMAB is designed to facilitate the rapid, serial generation of new monoclonal antibodies (“mAbs”) to keep pace with evolving viral threats.

On March 22, 2024, we received emergency use authorization (“EUA”) from the U.S. Food and Drug Administration (“FDA”) for PEMGARDA™ (pemivibart) injection, for intravenous use, a half-life extended investigational mAb, for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2.

PEMGARDA is our first mAb in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution. As the SARS-CoV-2 virus evolves over time, we anticipate leveraging our INVYMAB platform approach to periodically introduce new or engineered mAb candidates, an approach that would be analogous to the periodic updates made to influenza and COVID-19 vaccines. In January 2024, we nominated VYD2311, a mAb optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1, as a drug candidate, and we expect it will be the next pipeline program to advance into clinical development. In addition to developing candidates for COVID-19, we expect to apply our INVYMAB platform approach to produce lead molecules for other viral diseases, such as influenza.

Globally, COVID-19 has caused millions of deaths and lasting health problems in many survivors and remains a significant global health concern, particularly for immunocompromised individuals. 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 immunocompromised, and combating this disease will require a variety of effective and safe prevention and treatment options for years to come. By leveraging our capabilities, which we have developed through our experience with adintrevimab and pemivibart and nearly four years in the COVID-19 space, we aim to develop a continuous repertoire of SARS-CoV-2 neutralizing mAbs to keep pace with viral evolution.

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. Our focus in recent months has been and will continue to be supporting the commercialization of PEMGARDA and establishing streamlined development pathways that could enable us to efficiently introduce new or engineered mAb candidates targeting SARS-CoV-2, leveraging our INVYMAB platform approach and previously generated safety and efficacy data from our clinical trials of adintrevimab and/or pemivibart.

We rely on partnerships, external consultants and contract research organizations (“CROs”) to conduct discovery, nonclinical, preclinical, clinical and commercial activities. Additionally, we rely on contract testing laboratories and a contract development and manufacturing organization (“CDMO”) to execute our chemistry, manufacturing and controls 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, LLC (“Adimab”). We are focused on antibody discovery and use of Adimab’s platform technology, while building our internal capabilities. In addition, 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 primarily with net proceeds of \$464.7 million from sales of our preferred stock and with net proceeds of \$327.5 million from our initial public offering (“IPO”). Through December 31, 2023, we had not generated any revenue from any sources, including product sales. Our ability to generate product revenue sufficient

to achieve profitability will depend heavily on the successful development and commercialization of one or more of our product candidates, as they become authorized or approved.

Since our inception, we have incurred significant losses, including a net loss of \$198.6 million for the year ended December 31, 2023. As of December 31, 2023, we had an accumulated deficit of \$732.1 million. We may 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 commercialization efforts. Our expenses could increase substantially in connection with our ongoing activities, as we:

- initiate and conduct clinical trials of our product candidates;
- develop product candidates in new indications or patient populations;
- advance 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 regulatory authorizations or approvals and coverage and reimbursement for our product candidates, if authorized or approved;
- acquire or in-license other product candidates, intellectual property and/or technologies;
- further develop and validate our commercial-scale current Good Manufacturing Practices (“cGMP”) manufacturing process and manufacture material under cGMP at our contracted manufacturing facilities for clinical trials and potential commercial sales;
- maintain, expand, enforce, defend and protect our intellectual property portfolio;
- comply with regulatory requirements established by the applicable regulatory authorities;
- maintain and expand a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain regulatory authorization or approval;
- hire and retain personnel, including research, clinical, development, manufacturing, quality control, quality assurance, regulatory, scientific and other personnel; and
- incur additional legal, accounting and other expenses in operating as a public company.

We have implemented a go-to-market strategy, including building our own commercial organization and outsourcing to contract sales and marketing organizations. On March 22, 2024, we received EUA from the FDA for PEMGARDA, and as such, we will continue to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

As a result, we will require 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 funding or grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements. We may be unable to secure additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we are unable to secure additional funding when needed, we could be forced to curtail our planned operations and the pursuit of our growth strategy.

Because of the numerous risks and uncertainties associated with pharmaceutical product development and emergence of SARS-CoV-2 variants of concern (“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 authorization or approval for any of our product candidates other than PEMGARDA. 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 current operating plans and excluding any contribution from revenues or external financing, we believe that our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. As such, excluding any contribution from revenues or external financing, we will not have sufficient cash and cash equivalents to fund our operating expenses and capital requirements beyond one year from the issuance of our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, and therefore, we have

concluded that there is substantial doubt about our ability to continue as a going concern. 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 the section entitled “Liquidity and Capital Resources” for more information.

Components of Our Results of Operations

Revenue

Through December 31, 2023, we had not generated any revenue from product sales or any other sources. We expect to generate revenue from sales of PEMGARDA, which received EUA from the FDA in March 2024. If our development efforts for other product candidates are also successful and result in regulatory authorization or approval or collaboration or license agreements with third parties, we may also generate revenue in the future from other 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 generates a significant amount of research and development costs. Research and development expenses represent costs incurred by us for:

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

Such costs consist of:

- personnel-related expenses, including salaries, bonuses, benefits, third-party fees 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, nonclinical and preclinical studies and clinical trials of our product candidates and research programs;
- costs of procuring manufactured product candidates for use in nonclinical studies, preclinical studies, clinical trials and for commercial supply, prior to receiving authorization or approval, from a third-party CDMO;
- 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 a CDMO, CROs and consultants in connection with our nonclinical studies, preclinical studies, clinical trials and product manufacturing. 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 will increase as we continue to advance PEMGARDA and as we expect to advance VYD2311 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 authorization or approval 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;
- our ability to maintain compliance with regulatory requirements, including current Good Clinical Practices, current Good Laboratory Practices and cGMPs, and to comply effectively with other rules, regulations and procedures applicable to the development and sale of pharmaceutical products;
- timely receipt of regulatory authorizations or approvals from applicable regulatory authorities;
- 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, including as a result of any public health crisis.

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. Secretary of the Department of Health and Human Services (“HHS”), the FDA has the authority to issue an EUA. While the COVID-19 public health emergency declared by HHS under the Public Health Service Act expired on May 11, 2023, this does not impact the FDA’s ability to authorize COVID-19 drugs and biological products for emergency use. On March 22, 2024, we received EUA from the FDA for PEMGARDA. 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 other 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, such as the EUA received for PEMGARDA, for an extended period of time. The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564 of the FDCA, unless the declaration is terminated or authorization revoked sooner.

Acquired In-Process Research and Development Expenses

Acquired in-process research and development (“IPR&D”) expenses consist primarily of costs of contingent milestone payments incurred 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 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 compensation-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 will 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 commercialization of any authorized or approved product candidates, such as PEMGARDA. We also anticipate 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 lease agreement for dedicated laboratory and office space in Newton, Massachusetts for research and development purposes. Through December 31, 2023, we have operated as a hybrid company with employees working at our corporate headquarters and remotely. We have not incurred material operating expenses for the rent, maintenance and insurance of facilities, or for the 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, which terminated in accordance with its terms in May 2023. Clive Meanwell, M.D. and Tamsin Berry, members of our board of directors, are Managing Partner and Limited Partner of PHP, respectively.

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

Other Income, Net

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

Income Taxes

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

We continue to monitor the manner in which countries will enact legislation to implement the Pillar Two framework proposed by the Organisation for Economic Co-operation and Development, which proposes a 15% global corporate minimum tax. As of December 31, 2023, various countries have enacted aspects of Pillar Two while committing to enact additional aspects in future years. While we do not expect these rules to have a material impact on our effective tax rate, we continue to monitor these initiatives on a global basis.

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and 2022:

(in thousands)	Year Ended December 31,	
	2023	2022
Operating expenses:		
Research and development	\$ 158,658	\$ 179,214
Acquired in-process research and development	4,975	4,400
Selling, general and administrative	49,125	47,044
Warrant expense	—	17,373
Total operating expenses	212,758	248,031
Loss from operations	(212,758)	(248,031)
Other income:		
Other income, net	14,115	6,714
Total other income, net	14,115	6,714
Net loss	\$ (198,643)	\$ (241,317)

Research and Development Expenses

(in thousands)	Year Ended December 31,	
	2023	2022
Direct, external research and development expenses by program:		
VYD222 ⁽¹⁾	\$ 96,695	\$ —
Adintrevimab	3,857	106,024
VYD2311 ⁽²⁾	1,425	—
NVD200 ⁽³⁾	—	19,665
Unallocated research and development expenses:		
Personnel related (including stock-based compensation)	30,074	37,181
External discovery-related and other costs	26,607	16,344
Total research and development expenses	\$ 158,658	\$ 179,214

⁽¹⁾ In March 2023, we announced the nomination of VYD222 as a novel mAb therapeutic option for COVID-19.

⁽²⁾ In March 2024, we announced the nomination of VYD2311 as a novel mAb therapeutic option for COVID-19.

⁽³⁾ NVD200, a combination product that we previously nominated for clinical advancement, includes costs associated with VYD222 and other mAbs evaluated for potential advancement in 2022, prior to making the decision to prioritize VYD222 instead of NVD200 in 2023.

Research and development expenses were \$158.7 million for the year ended December 31, 2023, compared to \$179.2 million for the year ended December 31, 2022. The \$20.5 million decrease in research and development expenses was primarily due to the following:

- The decrease in direct costs related to our adintrevimab program of \$102.2 million was primarily due to a decrease in adintrevimab-related contract manufacturing and clinical trial costs after the nomination of our VYD222 product candidate in 2023.
- The increase in direct costs related to our VYD222 program was due to the nomination of our VYD222 product candidate in 2023. The costs were primarily related to clinical trial costs and contract manufacturing costs for commercial manufacturing.
- The increase in direct costs related to our VYD2311 program was due to the nomination of our VYD2311 product candidate in the first quarter of 2024. The costs were primarily related to contract manufacturing costs.

- In the first quarter of 2023, we prioritized the clinical development of VYD222 instead of NVD200 and therefore, there was no comparable spend for NVD200 during the year ended December 31, 2023.
- The decrease in personnel-related costs of \$7.1 million was primarily due to a reduction in headcount, including a decrease in stock-based compensation expense of \$6.6 million, partially offset by an increase in our bonus compensation in 2023.
- The increase in external discovery-related and other costs of \$10.3 million was primarily due to an increase in contract manufacturing costs related to our pipeline candidates of \$8.6 million and an increase in other external costs of \$2.3 million primarily due to services performed by PHP under the PHP Work Order, partially offset by a decrease in nonclinical and clinical trial costs of \$0.6 million.

Acquired In-Process Research and Development Expenses

Acquired IPR&D expenses of \$5.0 million for the year ended December 31, 2023 consisted of \$3.6 million incurred related to milestones under the Adimab Assignment Agreement and \$1.4 million incurred related to an option exercise fee, a drug discovery fee and an optimization completion fee under the Adimab Collaboration Agreement.

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 and \$1.4 million incurred related to an option exercise fee and drug discovery fees under the Adimab Collaboration Agreement.

Selling, General and Administrative Expenses

(in thousands)	Year Ended December 31,	
	2023	2022
Personnel related (including stock-based compensation)	\$ 27,323	\$ 21,153
Professional and consultant fees	19,833	23,884
Other	1,969	2,007
Total selling, general and administrative expenses	<u>\$ 49,125</u>	<u>\$ 47,044</u>

Selling, general and administrative expenses were \$49.1 million for the year ended December 31, 2023, compared to \$47.0 million for the year ended December 31, 2022. The \$2.1 million increase in selling, general and administrative expenses was primarily due to the following:

- The increase in personnel-related costs of \$6.2 million was primarily due to our bonus compensation in 2023 and 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 during the year ended December 31, 2022.
- The decrease in professional and consultant fees of \$4.1 million was primarily due to a \$3.9 million decrease in expenses related to corporate governance matters and a \$1.7 million decrease in director and officer insurance premiums, offset by a \$1.5 million increase in commercial costs.
- Other costs remained relatively consistent between periods.

Warrant Expense

No warrant expense was recognized for the year ended December 31, 2023.

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.

Other Income, Net

Other income, net for the year ended December 31, 2023 was \$14.1 million, consisting primarily of \$7.3 million of interest earned on our invested cash balances and \$6.8 million of net accretion of discounts related to our marketable securities.

Other income, 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.

Liquidity and Capital Resources

Sources of Liquidity

Through December 31, 2023, we had not generated any revenue from any sources, including from product sales, and have incurred significant operating losses and negative cash flows from operations. Although we received an EUA from the FDA for PEMGARDA in March 2024, to date, we have not yet generated any revenue from product sales and we may continue to incur significant expenses and potential operating losses for the foreseeable future as we commercialize PEMGARDA and advance the development of our other product candidates. To date, we have financed our operations primarily 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, 2023, we had cash and cash equivalents of \$200.6 million.

In December 2023, we entered into a Controlled Equity OfferingSM Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co., as sales agent (“Cantor”), pursuant to which we may, at our option, offer and sell shares of our common stock, with a sales value of up to \$75.0 million, from time to time, through Cantor, acting as sales agent, in transactions deemed to be “at the market offerings”, as defined in Rule 415 under the Securities Act. Cantor is entitled to a commission of 3% of the gross proceeds from any sales of such shares. In February 2024, we sold 9,000,000 shares of our common stock under the Sales Agreement at an average price of \$4.50 per share for \$39.3 million in net proceeds.

Cash Flows

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

(in thousands)	Year Ended December 31,	
	2023	2022
Net cash used in operating activities	\$ (173,164)	\$ (219,987)
Net cash provided by (used in) investing activities	280,684	(230,667)
Net cash provided by financing activities	1,045	506
Net increase (decrease) in cash and cash equivalents	<u>\$ 108,565</u>	<u>\$ (450,148)</u>

Operating Activities

During the year ended December 31, 2023, operating activities used \$173.2 million of cash, primarily due to our net loss of \$198.6 million, partially offset by non-cash charges of \$19.6 million and changes in our operating assets and liabilities of \$5.8 million. The changes in our operating assets and liabilities primarily consisted of a \$19.2 million increase in accrued expenses, a \$6.5 million increase in accounts payable and a \$0.7 million increase in non-current liabilities, partially offset by a \$18.9 million increase in prepaid expenses and other current assets and a \$1.6 million decrease in operating lease liabilities. The increases in accounts payable and accrued expenses were primarily due to the timing of vendor invoicing and payments. The increase in prepaid expenses and other current assets was primarily due to prepayments and deposits to WuXi Biologics for commercial manufacturing.

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 and changes in our operating assets and liabilities of \$16.1 million, partially offset by non-cash charges of \$37.5 million. The changes in our operating assets and liabilities primarily consisted of a \$34.9 million decrease in accrued expenses, a \$4.3 million decrease in accounts payable, and a \$0.5 million decrease in operating lease liabilities, partially offset by a \$20.4 million decrease in prepaid expenses and other current assets and a \$3.1 million decrease in other non-current assets. The decreases in accounts payable and accrued expenses were primarily due to the timing of vendor invoicing and payments. The decreases in prepaids expenses and other current assets and in other non-current assets were primarily due to our utilization of WuXi Biologics manufacturing deposits.

Investing Activities

Net cash provided by investing activities during the year ended December 31, 2023 consisted of \$372.5 million in maturities of marketable securities, offset by \$91.2 million in purchases of marketable securities and \$0.6 million in purchases of property and equipment.

Net cash used in investing activities during the year ended December 31, 2022 consisted of \$298.0 million in purchases of marketable securities and \$1.7 million in purchases of property and equipment, offset by \$69.0 million in maturities of marketable securities.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2023 primarily consisted of \$1.0 million from exercises of stock options and \$0.2 million from issuances of common stock under the Company's employee stock purchase plan.

Net cash provided by financing activities during the year ended December 31, 2022 primarily consisted of \$0.2 million from exercises of stock options and \$0.3 million from issuances of common stock under the Company's employee stock purchase plan.

Funding Requirements

Our expenses could increase in connection with our ongoing activities, particularly as we advance the nonclinical and preclinical studies and the clinical trials of our product candidates, including any associated manufacturing activities, and commercialization efforts. Our funding requirements and timing and amount of our operating expenditures will depend on many factors, including:

- the revenue received from sales of PEMGARDA and any other product candidates for which we receive future regulatory authorization or approval;
- the rate of progress in the development of our product candidates;
- the scope, progress, results and costs of discovery, nonclinical 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, intellectual property and/or technologies;
- 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 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 build and maintain a commercial infrastructure for product candidates for which we obtain regulatory authorization or approval;
- the timing and costs of securing sufficient manufacturing capacity for clinical and commercial supply of our product candidates, or the raw material components thereof;
- the costs and timing of commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive regulatory authorization or approval;
- the costs necessary to obtain regulatory authorizations or approvals, and the costs of post-marketing studies that could be required by regulatory authorities in jurisdictions where authorization or 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 and retain 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 costs of operating as a public company; and

- the impact of any business interruptions to our operations or to those of our third-party contractors resulting from any public health crisis.

Substantial Doubt about Ability to Continue as a Going Concern

In accordance with Accounting Standards Update 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), we are required to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern from the issuance date of our consolidated financial statements. Based on current operating plans and excluding any contribution from revenues or external financing, we believe that our cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2024. As such, excluding any contribution from revenues or external financing, we will not have sufficient cash and cash equivalents to fund our operating expenses and capital requirements beyond one year from the issuance of these consolidated financial statements, and therefore, we have concluded that there is substantial doubt about our ability to continue as a going concern. 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 funding or grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' 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. 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 acquisitions or capital expenditures or declaring dividends. 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 secure additional funds through contribution from revenues, 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 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 December 2020, we entered into a Commercial Manufacturing Services Agreement with WuXi Biologics, which was amended and restated in August 2021 and further amended and restated in September 2023 (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.

During the year ended December 31, 2023, we committed to noncancelable purchase obligations related to commercial drug substance and drug product manufacturing under the Commercial Manufacturing Agreement. As of December 31, 2023, the total remaining contractually binding commercial drug substance and drug product purchase obligations due to WuXi Biologics was \$33.9 million, which is expected to be paid in 2024. As of December 31, 2023, \$24.1 million related to the contractually binding commercial drug substance and drug product batches was included in accounts payable and accrued expenses, which is expected to be paid in 2024.

During the first quarter of 2024, we committed to additional noncancelable purchase obligations of \$24.7 million related to the procurement of materials to be used in future drug substance and drug product manufacturing under the Commercial Manufacturing Agreement.

During the first quarter of 2024, we committed to additional noncancelable purchase obligations of \$50.3 million related to commercial drug substance and drug product manufacturing under the Commercial Manufacturing Agreement.

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, 2023 were as follows (in thousands):

Year Ending December 31,	Operating Lease
2024	1,521
2025	430
2026	328
2027	—
Total lease payments	2,279
Present value adjustment	(114)
Present value of operating lease liability	<u>\$ 2,165</u>

Other Commitments

Under a separate cell line license agreement with WuXi Biologics, 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 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 under the agreement is \$24.6 million, of which a total of \$11.1 million has been achieved and paid as of December 31, 2023. In March 2023, we achieved the first specified milestone for the second product candidate under the agreement upon dosing of the first subject in a Phase 1 clinical trial evaluating VYD222, which obligated us to make a \$0.4 million milestone payment to Adimab, which was paid in May 2023. In September 2023, we achieved specified milestones for the second product candidate under the agreement upon dosing of the first subject in a pivotal clinical trial evaluating VYD222, which obligated us to make a \$3.2 million milestone payment to Adimab, which was paid in October 2023. The next potential milestone under the Adimab Assignment Agreement is a low single-digit million-dollar regulatory milestone. In addition, we are obligated to pay Adimab royalties of a mid-single-digit percentage based on our net sales of products under the agreement, beginning upon the first commercial sale of a product in accordance with the terms of the Adimab Assignment Agreement. 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 and September 2023, 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 could 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, through December 31, 2023, we were obligated to pay Adimab a quarterly fee 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 could be cancelled at our option at any time. In December 2023, pursuant to the terms of the Adimab Collaboration Agreement, we elected to decrease the scope of Adimab’s exclusivity obligations to cover only coronaviruses and obtained a corresponding

decrease in the quarterly fee. Effective January 2024, we are obligated to pay Adimab a quarterly fee of \$0.6 million, a decrease from the previous quarterly fee of \$1.3 million. 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. During the year ended December 31, 2023, we were obligated to make a \$1.0 million, a \$0.2 million, and a \$0.2 million payment to Adimab related to an option exercise fee, a drug delivery fee and an optimization completion fee, respectively. During the year ended December 31, 2022, we were obligated to make a \$1.0 million and a \$0.4 million payment to Adimab related to an option exercise fee and a drug delivery fee. 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 that achieves such milestones. The next potential milestone under the Adimab Collaboration Agreement is a low single-digit million dollar clinical milestone. We are 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. 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 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 Adimab Platform Transfer Agreement, we are obligated to pay Adimab an annual fee of single digit millions through June 2027, which allows us to receive from Adimab material improvements to the platform technology, including materially improved antibody optimization libraries, updates that provide new functionality to the platform, and software upgrades. 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 preclinical milestone. 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, subject to reductions specified under the Adimab Platform Transfer Agreement. 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 was effective for six months from November 2022 and terminated in accordance with its terms in May 2023. As compensation for the services and deliverables under the PHP Work Order, we paid 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.

We enter into other contracts in the normal course of business with 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. 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:

- our CROs in connection with performing nonclinical studies, preclinical studies and clinical trials;
- our CDMO related to the production of our product candidates for nonclinical studies, preclinical studies, clinical trials and commercial supply, prior to receiving authorization or approval; 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, CDMO 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 primarily issued awards with service-based vesting conditions through December 31, 2023. 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.

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:

- 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 our 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, 2023, 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, 2023, 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, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

During the three months ended December 31, 2023, no director or officer of the Company adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as each term is defined in Item 408 of Regulation S-K.

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 2024 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	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 May 25, 2023).
3.4	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).
3.5	Amendment No. 1 to the 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 May 25, 2023).
3.6	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 (incorporated by reference to Exhibit 4.3 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 23, 2023).
10.1+	2020 Equity Incentive Plan and Forms of Stock Option Grant Notice, Stock Option Agreement, and Exercise Notice (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 Stock Option Grant Notice, Stock Option Agreement, Exercise Notice, RSU Award Grant Notice and RSU Award Agreement.
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 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).
10.6+	First Amendment to the Employment Agreement of David Hering by and between the Registrant and David Hering, dated June 15, 2023 (incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on August 10, 2023).
10.7+	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).

- 10.8+ 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).
- 10.9*+# Employment Agreement by and between the Registrant and Peter Schmidt, dated November 9, 2020.
- 10.10*+# First Amendment to the Employment Agreement of Peter Schmidt by and between the Registrant and Peter Schmidt, dated December 6, 2022.
- 10.11*+ Employment Agreement by and between the Registrant and Stacy Price, dated February 3, 2023.
- 10.12*+ Employment Agreement by and between the Registrant and Robert Allen, dated March 14, 2023.
- 10.13+ Employment Agreement by and between the Registrant and William Duke, Jr. dated July 19, 2023 (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 September 5, 2023).
- 10.14*+# Employment Agreement by and between the Registrant and Julie Green, dated January 24, 2024.
- 10.15+ Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on May 11, 2023).
- 10.16†# 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).
- 10.17†# 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).
- 10.18† Amendment Number One to the Collaboration Agreement by and between the Registrant and Adimab, LLC, November 18, 2022 (incorporated by reference to Exhibit 10.13 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 23, 2023).
- 10.19† Amendment Number Two to the Collaboration Agreement by and between the Registrant and Adimab, LLC, dated September 19, 2023 (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 9, 2023).
- 10.20†# Second Amended and Restated Commercial Manufacturing Services Agreement by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated September 19, 2023 (incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q (File No. 001-40703), filed with the Securities and Exchange Commission on November 9, 2023).
- 10.21†# 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).
- 10.22† Amendment No. 1 to the Cell Line License Agreement by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated February 2, 2023 (incorporated by reference to Exhibit 10.16 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 23, 2023).
- 10.23*† Amendment No. 2 to the Cell Line License Agreement by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated March 13, 2024.
- 10.24† Clinical Master Services Agreement by between the Registrant and WuXi Biologics (Hong Kong) Limited, dated July 21, 2020 (incorporated by reference to Exhibit 10.17 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 23, 2023).
- 10.25 Controlled Equity OfferingSM Sales Agreement by and between the Registrant and Cantor Fitzgerald & Co., dated December 22, 2023 (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 22, 2023).
- 21.1 Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 23, 2023).
- 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.

- 97.1* Incentive Compensation Recovery Policy of the Registrant.
- 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 With Embedded Linkbase Documents
- 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 28, 2024

By: /s/ David Hering, M.B.A.

David Hering, M.B.A.
Chief Executive Officer and Director

Date: March 28, 2024

By: /s/ William Duke, Jr.

William Duke, Jr.
Chief Financial Officer

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.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ David Hering, M.B.A.</u> David Hering, M.B.A.	Chief Executive Officer & Director (Principal Executive Officer)	March 28, 2024
<u>/s/ William Duke, Jr.</u> William Duke, Jr.	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 28, 2024
<u>/s/ Marc Elia</u> Marc Elia	Chair of the Board of Directors	March 28, 2024
<u>/s/ Tamsin Berry</u> Tamsin Berry	Director	March 28, 2024
<u>/s/ Sara Cotter</u> Sara Cotter	Director	March 28, 2024
<u>/s/ Tomas Heyman</u> Tomas Heyman	Director	March 28, 2024
<u>/s/ Christine Lindenboom</u> Christine Lindenboom	Director	March 28, 2024
<u>/s/ Terrance McGuire</u> Terrance McGuire	Director	March 28, 2024
<u>/s/ Clive A. Meanwell, M.D.</u> Clive A. Meanwell, M.D.	Director	March 28, 2024
<u>/s/ Michael S. Wyzga</u> Michael S. Wyzga	Director	March 28, 2024

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	Page
Report of Independent Registered Public Accounting Firm (PCAOB ID 238).....	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Operations and Comprehensive Loss.....	F-4
Consolidated Statements of Stockholders' Equity (Deficit).....	F-5
Consolidated Statements of Cash Flows.....	F-7
Notes to Consolidated Financial Statements.....	F-8

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, 2023 and 2022, and the related consolidated statements of operations and comprehensive loss, of 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, 2023 and 2022, 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.

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

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

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our 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 28, 2024

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, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 200,641	\$ 92,076
Marketable securities	—	279,915
Prepaid expenses and other current assets	24,240	4,926
Total current assets	224,881	376,917
Property and equipment, net	1,896	2,282
Operating lease right-of-use assets	2,229	3,777
Other non-current assets	175	191
Total assets	<u>\$ 229,181</u>	<u>\$ 383,167</u>
Liabilities, Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,953	\$ 1,517
Accrued expenses	40,860	21,911
Operating lease liabilities, current	1,443	1,559
Other current liability	35	44
Total current liabilities	50,291	25,031
Operating lease liabilities, non-current	722	2,165
Other non-current liability	700	—
Early-exercise liability	—	1
Total liabilities	51,713	27,197
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, 2023 and December 31, 2022	—	—
Common stock, \$0.0001 par value; 1,000,000,000 shares authorized, 110,160,684 shares issued and outstanding at December 31, 2023; 109,044,046 shares issued and outstanding at December 31, 2022	11	11
Additional paid-in capital	909,539	889,657
Accumulated other comprehensive loss	(13)	(272)
Accumulated deficit	(732,069)	(533,426)
Total stockholders' equity	177,468	355,970
Total liabilities, preferred stock and stockholders' equity	<u>\$ 229,181</u>	<u>\$ 383,167</u>

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,	
	2023	2022
Operating expenses:		
Research and development ⁽¹⁾	\$ 158,658	\$ 179,214
Acquired in-process research and development ⁽²⁾	4,975	4,400
Selling, general and administrative	49,125	47,044
Warrant expense ⁽³⁾	—	17,373
Total operating expenses	212,758	248,031
Loss from operations	(212,758)	(248,031)
Other income:		
Other income, net	14,115	6,714
Total other income, net	14,115	6,714
Net loss	(198,643)	(241,317)
Other comprehensive income (loss)		
Unrealized gain (loss) on available-for-sale securities, net of tax	259	(264)
Comprehensive loss	\$ (198,384)	\$ (241,581)
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.81)	\$ (2.23)
Weighted-average common shares outstanding, basic and diluted	109,526,053	108,268,289

- (1) Includes related-party amounts of \$8,418 and \$8,154 for the years ended December 31, 2023 and 2022, respectively (see Note 15).
- (2) Includes related-party amounts of \$4,975 and \$4,400 for the years ended December 31, 2023 and 2022, respectively (see Note 15).
- (3) Includes related-party amounts of \$0 and \$17,373 for the years ended December 31, 2023 and 2022, respectively (see Note 15).

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

INVIVYD, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2022	109,044,046	\$ 11	—	\$ —	\$ 889,657	\$ (272)	\$ (533,426)	\$ 355,970
Exercise of stock options	1,224,330	—	—	—	955	—	—	955
Repurchase of unvested restricted common stock	(285,167)	—	285,167	—	—	—	—	—
Retirement of treasury stock	—	—	(285,167)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	18,685	—	—	18,685
Issuance of common stock under the employee stock purchase plan	177,475	—	—	—	240	—	—	240
Vesting of restricted common stock from early-exercised options	—	—	—	—	2	—	—	2
Unrealized gain on available-for-sale securities, net of tax	—	—	—	—	—	259	—	259
Net loss	—	—	—	—	—	—	(198,643)	(198,643)
Balances at December 31, 2023	110,160,684	\$ 11	—	\$ —	\$ 909,539	\$ (13)	\$ (732,069)	\$ 177,468

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

INVIVYD, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balances at December 31, 2021	11				850,125	(8)	(292,109)	\$ 558,019
Issuance of warrants for common stock	—	—	468,751	\$ —	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	\$ —	—	\$ —	889,657	(272)	(533,426)	\$ 355,970

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

INVIVYD, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
Cash flows from operating activities:		
Net loss	\$ (198,643)	\$ (241,317)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	18,685	21,648
Warrant expense	—	17,373
Net amortization of premiums and accretion of discounts on marketable securities	(1,122)	(2,023)
Amortization of operating lease right-of-use assets	1,548	421
Depreciation expense	480	41
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(18,892)	20,367
Other non-current assets	16	3,106
Accounts payable	6,471	(4,300)
Accrued expenses	19,162	(34,867)
Operating lease liabilities	(1,559)	(475)
Other current liabilities	(10)	44
Other non-current liabilities	700	(5)
Net cash used in operating activities	<u>(173,164)</u>	<u>(219,987)</u>
Cash flows from investing activities:		
Purchases of marketable securities	(91,202)	(297,962)
Maturities of marketable securities	372,501	69,000
Purchases of property and equipment	(615)	(1,705)
Net cash provided by (used in) investing activities	<u>280,684</u>	<u>(230,667)</u>
Cash flows from financing activities:		
Proceeds from exercises of stock options	955	241
Proceeds from issuance of common stock under the employee stock purchase plan	240	269
Payments for offering costs	(149)	—
Payments for repurchases of unvested restricted common stock	(1)	(4)
Net cash provided by financing activities	<u>1,045</u>	<u>506</u>
Net increase (decrease) in cash and cash equivalents	108,565	(450,148)
Cash and cash equivalents at beginning of period	92,076	542,224
Cash and cash equivalents at end of period	<u>\$ 200,641</u>	<u>\$ 92,076</u>
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	\$ 14	\$ 535
Deferred offering costs in accrued expenses	\$ 273	\$ —

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

INVIVYD, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of the Business and Basis of Presentation

Invivyd, Inc. is a commercial-stage 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. The Company's proprietary INVYMAB™ platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering. INVYMAB is designed to facilitate the rapid, serial generation of new monoclonal antibodies ("mAbs") to keep pace with evolving viral threats.

On March 22, 2024, the Company received emergency use authorization ("EUA") from the U.S. Food and Drug Administration ("FDA") for PEMGARDA™ (pemivibart) injection, for intravenous use, a half-life extended investigational mAb, for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2.

PEMGARDA is the Company's first mAb in a planned series of innovative mAb candidates designed to keep pace with SARS-CoV-2 viral evolution. As the SARS-CoV-2 virus evolves over time, the Company anticipates leveraging its INVYMAB platform approach to periodically introduce new or engineered mAb candidates, an approach that would be analogous to the periodic updates made to influenza and COVID-19 vaccines. In January 2024, the Company nominated VYD2311, a mAb optimized for neutralization potency against recent SARS-CoV-2 lineages such as BA.2.86 and JN.1, as a drug candidate, and the Company expects it will be the next pipeline program to advance into clinical development. In addition to developing candidates for COVID-19, the Company expects to apply its INVYMAB platform approach to produce lead molecules for other viral diseases, such as influenza.

The Company was incorporated in the State of Delaware in June 2020. The Company operates as a hybrid company with employees working at its corporate headquarters in Waltham, Massachusetts and remotely. In June 2022, and subsequently amended in September 2022, the Company entered into a lease for dedicated laboratory and office space in Newton, Massachusetts for research and development purposes. In 2022, the Company expanded its research team in order to enable internal discovery and development of its mAb candidates, while continuing to leverage the Company's existing partnership with Adimab, LLC ("Adimab"). The Company is focused on antibody discovery and use of Adimab's platform technology while building its own internal capabilities. In addition, the Company performs research and development activities internally and engages third parties, including 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 companies in the biopharmaceutical industry, including, but not limited to, completing clinical trials, the ability to raise additional capital to fund operations, obtaining regulatory authorization or approval for product candidates, market acceptance of products, competition from other products, protection of proprietary intellectual property, compliance with government regulations, 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.

Through December 31, 2023, the Company has not generated any revenue. To date, the Company has received regulatory authorization for only one product candidate, PEMGARDA, which has not been approved, but has been authorized for emergency use by the FDA under an EUA, for pre-exposure prophylaxis of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg). All of its other product candidates, other than adintrevimab, are currently in preclinical development. The Company's additional product candidates require significant additional research and development efforts, including extensive clinical testing, and regulatory authorization or approval prior to potential 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 substantial revenue from product sales to be able to fund its operating expenses and capital requirements.

Substantial Doubt about Ability to Continue as a Going Concern

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 ("IPO"). The Company has incurred losses and negative cash flows from operations since its inception,

including a net loss of \$198.6 million for the year ended December 31, 2023. As of December 31, 2023, the Company had an accumulated deficit of \$732.1 million. The Company may continue to generate operating losses for the foreseeable future.

In February 2024, the Company sold 9,000,000 shares of its common stock under the Sales Agreement (defined below) at an average price of \$4.50 per share for \$39.3 million in net proceeds.

Based on current operating plans and excluding any contribution from revenues or external financing, the Company believes that its existing cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2024. As such, excluding any contribution from revenues or external financing, the Company will not have sufficient cash and cash equivalents to fund its operating expenses and capital requirements beyond one year from the issuance of these consolidated financial statements, and therefore, the Company has concluded that there is substantial doubt about its ability to continue as a going concern.

The Company will require additional funding through a combination of contribution from revenues, equity offerings, government or private-party grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements to finance its future operations. 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 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.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. 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 U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, research and development expenses and related prepaid or accrued costs and stock-based compensation expense. The Company bases its estimates on historical experience, known trends and other market-specific or relevant factors it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates as there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ materially from those estimates or assumptions.

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

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. As of December 31, 2023, the Company invested its excess cash in money market funds that are subject to minimal credit and market risks. The Company maintains its existing cash and cash equivalents at three 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 existing cash and cash equivalents beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party organizations to manufacture and process its product candidates for its development programs. In particular, the Company relies on a single third-party contract manufacturer to produce and process its product candidates and to manufacture supply of its product candidates for preclinical and clinical activities. 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 (see Note 9). 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 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, 2023, 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 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

Effective January 1, 2023, the Company adopted ASU No. 2016-13 ("ASU 2016-13"), ASC 326, Financial Instruments-Credit Losses: Measurement of Credit Losses on Financial Instruments, using the effective date method. As the Company had never recorded any other-than-temporary-impairment adjustments to its available-for-sale debt securities prior to the effective date, no transition provisions were applicable to the Company.

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 as "available-for-sale" pursuant to ASC 320, 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 during the years ended December 31, 2023 or 2022.

The Company assesses its available-for-sale debt securities under the available-for-sale debt security impairment model in ASC 326, Financial Instruments-Credit Losses, as of each reporting date in order to determine if a portion of any decline in fair value below carrying value recognized on its available-for-sale debt securities is the result of a credit loss. The Company records credit losses in the consolidated statements of operations and comprehensive loss as credit loss expense within other income (expense), net, which is limited to the difference between the fair value and the amortized cost of the security. To date, the Company has not recorded any credit losses on its available-for-sale debt securities.

Accrued interest receivable related to the Company's available-for-sale debt securities is presented within prepaid expenses and other current assets on the Company's consolidated balance sheets. The Company has elected the practical

expedient available to exclude accrued interest receivable from both the fair value and the amortized cost basis of available-for-sale debt securities for the purposes of identifying and measuring any impairment. The Company writes off accrued interest receivable once it has determined that the asset is not realizable. Any write offs of accrued interest receivable are recorded by reversing interest income, recognizing credit loss expense, or a combination of both. To date, the Company has not written off any accrued interest receivables associated with its marketable securities.

Fair Value Measurements

Certain assets of the Company are carried at fair value under U.S. 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, 2023 and 2022.

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.

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 nonclinical studies, preclinical studies and clinical trials as well as to manufacture research and development materials for use in such studies and trials and for commercial supply; 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 clinical research organizations (“CROs”) and a contract manufacturing organization. With the exception of the Company’s commercial manufacturing arrangement with WuXi Biologics (Hong Kong) Limited (see Note 9), these agreements are generally cancellable. 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 primarily issued awards with service-based vesting conditions through December 31, 2023.

Compensation expense for awards granted to employees and directors for their service on the board of directors is recognized on a straight-line basis over the requisite service period of the respective award, which is generally the vesting period of the award. Compensation expense for awards granted to non-employees is recognized in the same period and manner as if the Company had paid cash for the goods or services provided, which is generally the vesting period of the award. The Company accounts for forfeitures of stock-based awards as they occur.

The Company classifies stock-based compensation expense in its statements of operations and comprehensive loss in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified.

Income Taxes

The Company accounts for income taxes using the asset and liability method, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined on the basis of the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income, and to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of the deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the consolidated financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely than not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the consolidated financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties. The Company had no amounts accrued for interest and penalties on its consolidated balance sheets as of December 31, 2023 and 2022.

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, 2023 and 2022, the Company's only element of other comprehensive loss was unrealized gains and 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. There is no allocation required under the two-class method during periods of loss since the participating securities do not have a contractual obligation to share in the losses of the Company.

Basic net income (loss) per share attributable to common stockholders is computed by dividing the net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period, excluding shares of unvested restricted common stock. Diluted net income (loss) per share attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net income (loss) per share attributable to common stockholders is computed by dividing the diluted net income (loss) attributable to common stockholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares. For the purposes of this calculation, the Company's outstanding stock options 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.

On January 1, 2023, the Company adopted ASU No. 2016-13 ("ASU 2016-13"), Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments. ASU 2016-13 requires measurement and recognition of expected credit losses for financial assets. In April 2019, the FASB issued clarification to ASU 2016-13 within ASU 2019-04, Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Topic 815, Derivatives and Hedging, and Topic 825, Financial Instruments, or ASU 2016-13. The guidance is effective for fiscal years beginning after December 15, 2022. The adoption of the standard was immaterial to the accompanying consolidated financial statements and related disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes—Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU 2023-09"). ASU 2023-09 modifies the rules on income tax disclosures to enhance the transparency and decision-usefulness of income tax disclosures, particularly in the rate reconciliation table and disclosures about income taxes paid. The amendments are intended to address investors' requests for income tax disclosures that provide more information to help them better understand an entity's exposure to potential changes in tax laws and the ensuing risks and opportunities and to assess income tax information that affects cash flow forecasts and capital allocation decisions. The guidance also eliminates certain existing disclosure requirements related to uncertain tax positions and unrecognized deferred tax liabilities. The guidance is effective for all entities for annual periods beginning after December 15, 2025. All entities should apply the guidance prospectively but have the option to apply it retrospectively. Early adoption is permitted. The Company is continuing to assess the timing of adoption and the potential impacts of ASC 2023-09 on the consolidated financial statements and related disclosures.

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 Company did not hold any available-for-sale marketable securities as of December 31, 2023.

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

December 31, 2022	Amortized Cost	Unrealized Gains	Unrealized Losses	Credit 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	<u>\$ 280,187</u>	<u>\$ 52</u>	<u>\$ (324)</u>	<u>\$ —</u>	<u>\$ 279,915</u>

No available-for-sale marketable securities held as of December 31, 2022 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, 2023:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	\$ 198,193	\$ —	\$ —	\$ 198,193
	<u>\$ 198,193</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 198,193</u>

	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
	<u>\$ 198,921</u>	<u>\$ 172,044</u>	<u>\$ —</u>	<u>\$ 370,965</u>

The money market funds were valued by the Company based on quoted market prices, which represent a Level 1 measurement within the fair value hierarchy.

There were no changes to the valuation methods during the years ended December 31, 2023 or 2022.

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, 2023 or 2022.

5. Prepaid Expenses and Other Current Assets

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

	December 31, 2023	December 31, 2022
Prepaid external research, development and manufacturing costs	\$ 19,962	\$ 843
Prepaid insurance	1,770	2,392
Prepaid compensation and other	1,575	1,314
Interest receivable	933	377
	<u>\$ 24,240</u>	<u>\$ 4,926</u>

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Accrued external research, development and manufacturing costs	\$ 28,151	\$ 13,955
Accrued professional and consultant fees	1,732	1,153
Accrued employee compensation	10,752	5,985
Other	225	818
	<u>\$ 40,860</u>	<u>\$ 21,911</u>

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. 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. During the years ended December 31, 2023 and 2022, the Company recognized \$0 and \$0.6 million, respectively, of research and development expense with respect to services performed by Adimab on the Company’s behalf under the Adimab Assignment Agreement. Please refer to Note 15 for additional information.

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, of which a total of \$11.1 million has been achieved and paid as of December 31, 2023; however, milestone payments do not accrue for certain *in vitro* diagnostic devices consisting of or containing CoV Antibodies.

In March 2023, the Company achieved the first specified milestone for the second product candidate under the Adimab Assignment Agreement upon dosing of the first subject in a Phase 1 clinical trial evaluating VYD222, which obligated the Company to make a \$0.4 million milestone payment to Adimab, which was paid in May 2023. In September 2023, the Company achieved specified milestones for the second product candidate under the Adimab Assignment Agreement upon dosing of the first subject in a pivotal clinical trial evaluating VYD222, which obligated the Company to make a \$3.2 million milestone payment to Adimab, which was paid in October 2023. During the year ended December 31, 2023, the Company recognized \$3.6 million of IPR&D expense with respect to contingent consideration payable under the Adimab Assignment Agreement. During 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. The next potential milestone under the Adimab Assignment Agreement is a low single-digit million-dollar regulatory milestone, which was not considered probable under U.S. GAAP and therefore, no expense was recognized as of December 31, 2023.

The Company is obligated to pay Adimab royalties of a mid-single-digit percentage based on net sales of any Products, beginning upon the first commercial sale of a Product in accordance with the Adimab Assignment Agreement. 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 (the “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 milestone payments of \$11.1 million incurred through December 31, 2023, no other milestone, royalty or other contingent payments had become due to Adimab through December 31, 2023.

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 and September 2023 (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 could 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 agreed to pay Adimab a quarterly fee of \$1.3 million, which could be cancelled at the Company's option at any time. For so long as the Company was 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 agreed not to assist or direct certain third parties to discover or optimize antibodies intended to bind to coronaviruses or influenza viruses. Under the Adimab Collaboration Agreement, the Company could also elect to decrease the scope of Adimab's exclusivity obligations and obtain a corresponding decrease in the quarterly fee. In December 2023, the Company elected to decrease the scope of Adimab's exclusivity obligations to cover only coronaviruses, and obtained a corresponding decrease in the quarterly fee. Effective January 2024, the Company is obligated to pay Adimab a quarterly fee of \$0.6 million. For each of the years ended December 31, 2023 and 2022, the Company recognized \$5.2 million of research and development expense related to the quarterly fee.

For each agreed upon research program that is commenced, the Company is obligated to pay Adimab quarterly for its services performed during a given research program at a specified full-time equivalent rate; a discovery delivery fee of \$0.2 million; and an optimization completion fee of \$0.2 million. For each option exercised by the Company to commercialize a specific research program, the Company is obligated to pay Adimab an exercise fee of \$1.0 million. Amounts paid with respect to services performed by Adimab on the Company's behalf in each of the research programs under the Adimab Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. During the years ended December 31, 2023 and 2022, the Company recognized \$0.5 million and \$1.7 million, respectively, of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement. During the year ended December 31, 2023, the Company recognized \$1.0 million, \$0.2 million, and \$0.2 million of IPR&D expense related to an option exercise fee, a drug delivery fee and an optimization completion fee, respectively. During the year ended December 31, 2022, the Company recognized \$1.0 million and \$0.4 million of IPR&D expense related to an option exercise fee and a drug delivery fee, respectively. Please refer to Note 15 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 clinical milestone, which was not considered probable under U.S. GAAP and therefore, no expense was recognized as of December 31, 2023. 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, 2023, 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 IPR&D expense in the related period in which the services are performed or the related milestone is considered probable of achievement. Amounts paid with respect to services performed by Adimab on the Company's behalf under the Adimab

Collaboration Agreement are recognized as research and development expense as such amounts are incurred and services are rendered. Please refer to Note 15 for additional information.

Adimab Platform Transfer Agreement

In September 2022 (the “Adimab Platform Transfer Agreement 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 has been 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 Adimab Platform Transfer Agreement Effective Date, which allows 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 became due in September 2023 and was paid in October 2023. During the year ended December 31, 2023, the Company recognized a portion of the first annual fee as research and development expense. 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 preclinical milestone, which was not considered probable under U.S. GAAP and therefore, no expense was recognized as of December 31, 2023.

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, 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, 2023, 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 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 15 for additional information.

WuXi Biologics Cell Line License Agreement

In December 2020, as amended in February 2023 and March 2024, 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”).

In December 2020, the Company recognized an upfront fee of \$0.2 million 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, 2023, 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. The Company did not recognize any IPR&D expense under the Cell Line License Agreement during the years ended December 31, 2023 or 2022.

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 year ended December 31, 2023, the Company did not recognize any research and development expense with respect to services performed under the Research Agreement as it was terminated during 2022. During the year ended December 31, 2022, the Company recognized \$1.7 million of research and development expense with respect to services performed under the Research Agreement.

8. Population Health Partners

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 for an initial term of one year. The PHP MSA renews for subsequent periods, until terminated 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 was effective for six months from the PHP Effective Date and terminated in accordance with its terms in May 2023. 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 paid 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”).

During the years ended December 31, 2023 and 2022, the Company recognized \$2.2 million and \$0.8 million, respectively, of research and development expense related to the cash compensation paid to PHP. Please refer to Note 15 for additional information.

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 the Company's common stock, which was equal to the Nasdaq official closing price (as defined in the PHP Warrant) of a share of the Company's 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 the Company's 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 the Company's 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 the Company's 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 PHP 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 fundamental transaction 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 fundamental transaction 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 fundamental transaction 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 11 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 Limited 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):

	Year Ended December 31,	
	2023	2022
Lease cost:		
Operating lease cost	\$ 1,720	\$ 754
Variable lease cost	46	31
Total lease cost	<u>\$ 1,766</u>	<u>\$ 785</u>
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows related to operating leases	\$ 1,731	\$ 837

Future minimum lease payments under the noncancelable leases as of December 31, 2023 was as follows (in thousands):

Year Ending December 31,	Operating Lease
2024	1,521
2025	430
2026	328
2027	—
Total lease payments	2,279
Present value adjustment	(114)
Present value of operating lease liability	<u>\$ 2,165</u>

As of December 31, 2023, the Company's operating leases were measured using a weighted-average incremental borrowing rate of 6.0% over a weighted-average remaining lease term of 1.8 years.

As of December 31, 2022, the Company's operating leases were 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 liabilities are presented on the Company's consolidated balance sheet based on maturity dates. \$1.4 million is classified under "operating lease liabilities, current" for the portion due within twelve months, and \$0.7 million is classified under "operating lease liabilities, 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 was effective for six months from November 2022 and terminated in accordance with its terms in May 2023. As compensation for the services and deliverables under the PHP Work Order, the Company paid 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.

Clinical and Manufacturing Agreements

In December 2020, the Company entered into a Commercial Manufacturing Services Agreement with WuXi Biologics, which was amended and restated in August 2021 and further amended and restated in September 2023 (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.

During the year ended December 31, 2023, the Company committed to noncancelable purchase obligations related to commercial drug substance and drug product manufacturing under the Commercial Manufacturing Agreement. As of December 31, 2023, the total remaining contractually binding commercial drug substance and drug product purchase obligations due to WuXi Biologics was \$33.9 million, which is expected to be paid in 2024. As of December 31, 2023, \$24.1 million related to the contractually binding commercial drug substance and drug product batches was included in accounts payable and accrued expenses, which is expected to be paid in 2024.

During the first quarter of 2024, the Company committed to additional noncancelable purchase obligations of \$24.7 million related to the procurement of materials to be used in future drug substance and drug product manufacturing under the Commercial Manufacturing Agreement.

During the first quarter of 2024, the Company committed to additional noncancelable purchase obligations of \$50.3 million related to commercial drug substance and drug product manufacturing under the Commercial Manufacturing Agreement.

Unless earlier terminated, the Commercial Manufacturing Agreement remains in effect for an initial period of five years from the date of the last amendment and restatement of the agreement 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 timely cured after notice thereof. 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 timely cured after notice thereof. Until regulatory approval and future economic benefit is probable, the Company will continue to expense costs related to batches manufactured under the Commercial Manufacturing Agreement.

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, 2023 and 2022.

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.

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 court appointed lead plaintiffs for the action on June 28, 2023. On August 23, 2023, the lead plaintiffs filed an amended complaint that makes allegations similar to those in the original complaint and asserts the same claims against the same defendants as the original complaint. On October 19, 2023, the parties filed a joint stipulation to advise the court that the lead plaintiffs intended to seek leave to file a second amended complaint, and on November 22, 2023, the lead plaintiffs filed a second amended complaint that makes allegations similar to those in the prior complaints and asserts the same claims against the same defendants as the prior complaints. On January 12, 2024, the defendants filed a motion to dismiss the second

amended complaint in its entirety. The lead plaintiffs filed an opposition to the motion to dismiss on February 26, 2024, and the defendants filed a reply in further support of their motion to dismiss on March 27, 2024.

The Company believes that it 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.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to its vendors, lessors, CROs, contract development and manufacturing organizations (“CDMOs”), 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 executive 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. Common Stock

Shares Reserved for Future Issuance

As of December 31, 2023 the Company had reserved 43,048,016 shares of common stock for the exercise of outstanding stock options and the issuance of awards available for grant under the Company’s 2020 Equity Incentive Plan, 2021 Equity Incentive Plan and 2021 Employee Stock Purchase Plan (see Note 11).

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. As of December 31, 2023, \$325 million of the Company’s securities remained available for offer and sale under this shelf registration statement.

ATM Facility

In December 2023, the Company entered into a Controlled Equity OfferingSM Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co., as sales agent (“Cantor”), pursuant to which the Company may, at its option, offer and sell shares of its common stock, with a sales value of up to \$75.0 million, from time to time, through Cantor, acting as sales agent, in transactions deemed to be “at the market offerings”, as defined in Rule 415 under the Securities Act. Cantor is entitled to a commission of 3% of the gross proceeds from any sales of such shares. The Company did not sell any shares of its common stock through the year ended December 31, 2023. As of December 31, 2023, \$75.0 million remained available for sale under the Sales Agreement.

In February 2024, the Company sold 9,000,000 shares of its common stock under the Sales Agreement at an average price of \$4.50 per share for \$39.3 million in net proceeds.

Treasury Stock

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 consolidated balance sheets and consolidated statements of 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, and subsequently retired, 206,802 shares of unvested restricted common stock at the original purchase price upon a termination of service of an employee during the vesting period. The fair value of the repurchased common stock was insignificant. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

In May 2023, the Company repurchased 46,600 shares of unvested restricted common stock at the original purchase price upon a termination of service of an employee during the vesting period. The shares of common stock repurchased were recorded as treasury stock. The fair value of the repurchased common stock was insignificant. In June 2023, the Company retired the 46,600 shares of treasury stock. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

In October 2023, the Company repurchased 31,765 shares of unvested restricted common stock at the original purchase price upon a termination of service of an employee during the vesting period. The shares of common stock repurchased were recorded as treasury stock. The fair value of the repurchased common stock was insignificant. In December 2023, the Company retired the 31,765 shares of treasury stock. Upon retirement, the shares were redesignated as authorized but unissued shares of the Company's common stock.

11. Stock-Based Compensation

2020 Equity Incentive Plan

The Company's 2020 Equity Incentive Plan (the "2020 Plan") provides for the Company to grant incentive stock options, non-qualified stock options, restricted stock awards, restricted stock units and other stock-based awards to employees, members of the board of directors and consultants. The 2020 Plan is administered by the board of directors or, at the discretion of the board of directors, by a committee of the board of directors. The board of directors may also delegate to one or more officers of the Company the power to grant awards to employees and certain officers of the Company. The exercise prices, vesting and other restrictions are determined at the discretion of the board of directors, or its committee or any such officer if so delegated.

The exercise price for stock options granted may not be less than the fair market value of the Company's common stock on the date of grant, as determined by the board of directors, or at least 110% of the fair market value of the Company's common stock on the date of grant in the case of an incentive stock option granted to an employee who owns stock representing more than 10% of the voting power of all classes of stock as determined by the board of directors as of the date of grant. Prior to the 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, 2023, there were 4,318,810 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 pursuant to the evergreen provision thereof, 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 pursuant to the evergreen provision thereof. 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. On January 1, 2024, 3,304,821 shares of common stock were added to the shares authorized for issuance under the 2021 Plan, pursuant to the evergreen provision thereof, 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, 2023, there were an aggregate of 41,996,239 shares authorized to be issued under the 2020 Plan and the 2021 Plan, which included 4,318,810 and 18,746,704 shares authorized to be issued upon the exercise of outstanding stock option grants from the 2020 Plan and 2021 Plan, respectively, and 0 and 18,930,725 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:

	2023	2022
Expected term (in years)	5.9	6.0
Expected volatility	66.1%	71.8%
Risk-free interest rate	3.8%	2.7%
Expected dividend yield	—%	—%

Stock Option Activity

The following table summarizes the Company’s stock option activity since December 31, 2022:

	Number of Shares	Weighted- Average Exercise Price	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	23,239,391	\$ 7.01	7.9	\$ 1,594
Granted	9,862,389	\$ 2.36		
Exercised	(1,224,330)	\$ 0.78		
Forfeited	(8,811,936)	\$ 7.72		
Outstanding at December 31, 2023	<u>23,065,514</u>	\$ 5.08	8.7	\$ 24,745
Vested and expected to vest at December 31, 2023	23,065,514	\$ 5.08	8.7	\$ 24,745
Options exercisable at December 31, 2023	7,371,263	\$ 7.30	8.0	\$ 5,195

The weighted-average grant date fair value of stock options granted during the year ended December 31, 2023 and 2022 was \$1.46 and \$2.79, 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, 2023 and December 31, 2022.

The total intrinsic value of stock options exercised during the year ended December 31, 2023 and 2022 was \$0.8 million and \$1.0 million, respectively.

Early Exercise of Stock Options into Restricted Stock

The Company's restricted stock activity during the year ended December 31, 2023 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 to the 2020 Plan. 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.

A summary of the Company's unvested common stock from option early exercises that is subject to repurchase by the Company is as follows:

	Number of Shares
Unvested restricted stock at December 31, 2022	360,333
Issued	—
Vested	(75,166)
Repurchased	(285,167)
Unvested restricted stock at December 31, 2023	<u>—</u>

Proceeds from the early exercise of stock options are recorded as an early-exercise liability on the consolidated balance sheets. The liability for unvested common stock subject to repurchase is then reclassified to common stock and additional paid-in capital as the Company's repurchase right lapses. Shares issued pursuant to the early exercise of stock options are not considered to be outstanding for accounting purposes until the shares vest. As of December 31, 2023, there were no unvested shares of restricted stock remaining and therefore the liability related to the payments was \$0. As of December 31, 2022, 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):

	2023	2022
Research and development	\$ 6,240	\$ 12,800
Selling, general and administrative	12,445	8,848
	<u>\$ 18,685</u>	<u>\$ 21,648</u>

As of December 31, 2023, total unrecognized stock-based compensation expense related to unvested stock-based awards was \$37.6 million, which is expected to be recognized over a weighted-average period of 2.5 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 290,996 shares issued under the 2021 ESPP as of December 31, 2023. 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, pursuant to the evergreen provision thereof, 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, 2024 or January 1, 2023, pursuant to the evergreen provision thereof, as determined by the Company's board of directors. The first offering under the 2021 ESPP was June 6, 2022. As of December 31, 2023, 1,051,777 shares remained available for issuance under the 2021 ESPP. During the year ended December 31, 2023, 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.

There were no warrants issued during the year ended December 31, 2023. As of December 31, 2023, there were 6,824,712 warrants outstanding at a weighted average exercise price of \$3.48, with a weighted-average remaining contractual term of 8.88 years.

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:

	<u>Year Ended December 31,</u>	
	<u>2022</u>	
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 in November 2022.

12. Income Taxes

During the years ended December 31, 2023 and 2022, 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:

	<u>Year Ended December 31,</u>	
	<u>2023</u>	<u>2022</u>
Federal statutory income tax rate	(21.0)%	(21.0)%
State income taxes, net of federal benefit	(11.0)	(3.5)
Federal research and development tax credits	(3.0)	(4.1)
Stock-based compensation	0.3	0.3
Change in deferred tax asset valuation allowance	34.8	28.3
Other	(0.1)	—
Effective income tax rate	—%	—%

The Company's net deferred tax assets consisted of the following (in thousands):

	Year Ended December 31,	
	2023	2022
Deferred tax assets:		
Net operating loss carryforwards	\$ 76,441	\$ 61,653
Capitalized research and development	74,115	36,550
Research and development tax credit carryforwards	24,313	16,901
Stock-based compensation expense	13,921	8,308
Warrant expense	4,781	4,066
Intangibles	4,217	2,602
Operating lease liabilities	569	871
Other	2,727	1,269
Total gross deferred tax assets	201,084	132,220
Valuation allowance	(200,385)	(131,325)
Total deferred tax assets	\$ 699	\$ 895
Deferred tax liabilities:		
Operating lease right-of-use assets	\$ (585)	\$ (884)
Depreciation expense	(114)	(11)
Total deferred tax liabilities	(699)	(895)
Total net deferred tax assets	\$ —	\$ —

As of December 31, 2023 and 2022, the Company had U.S. federal NOL carryforwards of \$318.6 million and \$263.7 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, 2023, the Company had state NOL carryforwards of \$153.8 million, which may be available to reduce future taxable income, of which \$9.6 million have an indefinite carryforward period while the remaining \$144.2 million begin to expire in 2032. As of December 31, 2023, the Company also had U.S. federal and state research and development tax credit carryforwards of \$19.3 million and \$6.4 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, 2023 and 2022. Management reevaluates the positive and negative evidence at each reporting period. During the years ended December 31, 2023 and 2022, the Company increased its valuation allowance by \$69.1 million and \$68.3 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, 2023 and 2022, the Company has not recorded any uncertain tax positions or related interest and penalties.

The Company files income tax returns in the U.S. federal and various state jurisdictions and is not currently under examination by any taxing authority for any open tax year. Due to NOL carryforwards, all years remain open for income tax examination. To the extent the Company has tax attribute carryforwards, the tax years in which the attribute was generated may still be adjusted upon examination by the federal or state tax authorities to the extent utilized in a future period. No federal or state tax audits are currently in process.

13. Defined Contribution Plan

The Company maintains a 401(k) Plan (the “401(k) Plan”) for the benefit of eligible employees. The 401(k) Plan is a defined contribution plan under Section 401(k) of the Internal Revenue Code of 1986, 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 both the years ended December 31, 2023 and 2022, the Company contributed \$0.8 million to the 401(k) Plan.

14. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows (in thousands, except share and per share amounts):

	2023	2022
Numerator:		
Net loss attributable to common stockholders	\$ (198,643)	\$ (241,317)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	109,526,053	108,268,289
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (1.81)</u>	<u>\$ (2.23)</u>

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:

	2023	2022
Stock options to purchase common stock	23,065,514	23,239,391
Unvested restricted common stock	—	360,333
Warrants to purchase common stock	6,824,712	6,824,712
	<u>29,890,226</u>	<u>30,424,436</u>

15. Related Party Transactions

As of December 31, 2023 and December 31, 2022, an aggregate of \$0.7 million and \$0.3 million, respectively, was due to Adimab under the Adimab Assignment Agreement, the Adimab Collaboration Agreement, the Adimab Platform Transfer Agreement and the Adimab DNA Sequencing Services Agreement (as defined below) by the Company. As of December 31, 2023 and 2022, no amounts were due to the Company from Adimab under the Adimab Assignment Agreement, the Adimab Collaboration Agreement, the Adimab Platform Transfer Agreement or the Adimab DNA Sequencing Services Agreement.

Adimab Assignment Agreement

Under the Adimab Assignment Agreement, Adimab, a principal stockholder of the Company, 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).

During the year ended December 31, 2023, the Company recognized \$3.6 million as IPR&D expense with respect to milestones payable under the Adimab Assignment Agreement. During the year ended December 31, 2022, the Company did not recognize any IPR&D expense with respect to milestones payable under the Adimab Assignment Agreement.

During the year ended December 31, 2023, the Company did not recognize any research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement. During the year ended December 31, 2022, the Company recognized \$0.6 million of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Assignment Agreement.

Adimab Collaboration Agreement

Under the Adimab Collaboration Agreement, the Company is obligated to pay Adimab for certain fees, milestones and royalty payments (see Note 7).

During both the years ended December 31, 2023 and 2022, the Company recognized \$5.2 million of research and development expense related to the quarterly fee under the Adimab Collaboration Agreement.

During the years ended December 31, 2023 and 2022, the Company recognized \$0.5 million and \$1.7 million, respectively, of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab Collaboration Agreement.

During both the years ended December 31, 2023 and 2022, the Company recognized \$1.0 million of IPR&D expense related to an option exercise fee under the Adimab Collaboration Agreement.

During the years ended December 31, 2023 and 2022, the Company recognized \$0.2 million and \$0.4 million, respectively, of IPR&D expense related to drug delivery fees under the Adimab Collaboration Agreement.

During the year ended December 31, 2023, the Company recognized \$0.2 million of IPR&D expense related to an optimization completion fee under the Adimab Collaboration Agreement. During the year ended December 31, 2022, the Company did not recognize any IPR&D expense related to an optimization completion fee under the Adimab Collaboration Agreement.

Adimab Platform Transfer Agreement

Under the Adimab Platform Transfer Agreement, the Company is obligated to pay Adimab for certain fees, milestones and royalty payments (see Note 7).

During the year ended December 31, 2023, the Company recognized a portion of the first annual fee as research and development expense under the Adimab Platform Transfer Agreement.

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 under the Adimab Platform Transfer Agreement.

Adimab DNA Sequencing Services Agreement

In May 2023, as amended in January 2024, the Company entered into a Services Agreement with Adimab for Adimab to perform DNA sequencing on yeast samples provided by the Company, and the delivery of the resulting data and information to the Company (the "Adimab DNA Sequencing Services Agreement"). In exchange for the services performed, the Company will pay Adimab a fee for each yeast-derived DNA template sample present in the well within the sequencer plate.

During the year ended December 31, 2023, the Company recognized less than \$0.1 million of research and development expense with respect to services performed by Adimab on the Company's behalf under the Adimab DNA Sequencing Services Agreement.

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.

During the year ended December 31, 2023, the Company did not recognize any expense related to the Mithril Group. As of December 31, 2023, 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 was 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 Limited Partner of PHP, respectively.

During the years ended December 31, 2023 and 2022, the Company recognized \$2.2 million and \$0.8 million, respectively, of research and development expense related to services performed by PHP in connection with the PHP Work Order, which terminated in accordance with its terms in May 2023.

During the year ended December 31, 2023, the Company did not recognize any warrant expense. 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, 2023, no amounts were due to PHP by the Company, and no amounts were due from PHP to the Company. 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.