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, 2025

or

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

Commission File Number 001-40703

INVIVYD, INC.

(Exact name of Registrant as specified in its Charter)

Delaware	**85-1403134**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
209 Church Street **New Haven, CT**	
(Address of principal executive offices)	**06510** **(Zip Code)**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of June 30, 2025, 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 $50.9 million based on the closing price of the registrant's common stock on June 30, 2025. 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 February 26, 2026 was 282,594,729.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive proxy statement for its 2026 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, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Forward-looking statements include, but are not limited to, statements regarding our management team's expectations, hopes, beliefs, intentions or strategies regarding the future, projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, and are not guarantees of future performance. The words "may," "anticipate," "believe," "could," "expect," "intends," "might," "plan," "possible," "potential," "aim," "predict," "project," "should," "will," "would" and similar expressions may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. These statements speak only as of the date of this Annual Report on Form 10-K and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements include, without limitation, statements about the following:

- our plans related to the commercialization of 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;
- our expectations related to VYD2311, our next generation monoclonal antibody ("mAb") candidate for COVID-19, the REVOLUTION clinical program for VYD2311 and the potential of VYD2311 to offer the ability to deliver clinically meaningful titer levels through more healthcare system- and patient-friendly means;
- our plans to periodically introduce new mAb candidates as the SARS-CoV-2 virus evolves over time;
- 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 devotion to delivering protection from serious viral infectious diseases, and our commitment to developing a robust pipeline of product candidates that could be used in prevention or treatment of serious viral infectious diseases, starting with COVID-19 and expanding into other high-need indications, such as respiratory syncytial virus ("RSV") and measles;
- our strategy to advance differentiated product candidates to address infectious diseases through internal research and collaborations;
- our goal of establishing streamlined development pathways to efficiently introduce new mAb candidates targeting SARS-CoV-2;
- 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 expectation of continued reliance 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;
- manufacturing capabilities and strategy, and our expectations regarding supply and demand of our product candidates;
- our ability to successfully commercialize our product candidates, if authorized or approved, including our distribution capabilities and strategy;
- our ability to deliver new product candidates that exert continuous pharmaceutical activity in the face of viral evolution and that can be updated quickly as necessary via our bespoke platform;
- our expectations regarding the SPEAR (Spike Protein Elimination and Recovery) Study Group, including its anticipated focus, goals and plans;

- 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 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 and are highly dependent on the commercial success of our only authorized product, PEMGARDA, for the foreseeable future, until VYD2311 or any other product candidate is authorized or approved and successfully commercialized, if ever. We may not achieve or maintain profitability.
- We have a limited operating history and limited experience with 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 support our continuing operations and pursue our growth strategy. In April 2025, we entered into a Term Facility (as defined below); however, if we are unable to satisfy certain conditions of the Loan Agreement (as defined below), we will be unable to draw down the amounts of such Term Facility. If we are unable to secure and access 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 mAbs for 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. 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 substantially harmed.
- Because our COVID-19 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 COVID-19 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.
- There can be no assurance that the public health emergency in the U.S. declared under Section 564 of the Federal Food, Drug, and Cosmetic Act (the "FDCA") permitting the FDA to authorize COVID-19 drugs and biologics for emergency use, such as the EUA for PEMGARDA, will continue to be in place for an extended period of time. If the EUA for PEMGARDA is terminated or revoked, we will be unable to sell PEMGARDA and instead would need to pursue traditional regulatory approval processes, which are lengthy, time consuming and inherently unpredictable, and which we may determine not to pursue. If we are not able to maintain regulatory authorization for PEMGARDA, our business will be substantially harmed.
- We may not succeed in obtaining the regulatory approval necessary to sell our product candidates.
- 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 or other infectious diseases 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 of our clinical trials, which could in turn delay or prevent our receipt of necessary regulatory authorizations or 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, difficult and time-consuming to manufacture, and we currently rely on a single contract manufacturer for our COVID-19 product candidates. We could experience manufacturing problems, may be unable to access desired future 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 COVID-19 product candidates for clinical trials and commercial supply, 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, acceptable pricing terms, 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 may be lengthy and expensive, which could harm our future business prospects.
- Our product candidates 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 continue 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, including PEMGARDA, 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.
- There can be no assurance that we will continue to be able to comply with the continued listing standards of Nasdaq.

General Risk Factors

- Unfavorable global economic conditions and geopolitical events, including as a result of trade tensions between the U.S. and China, could adversely affect our business, financial condition or results of operations, including conduct of our clinical trials and our manufacturing activities.

PART I

Item 1. Business.

Overview

Invivyd, Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of monoclonal antibody ("mAb") therapies for the prevention and treatment of serious viral infectious diseases. We are devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2, the virus that causes COVID-19. PEMGARDA® (pemivibart) is our first mAb to receive regulatory authorization and was designed to exert continuous pharmaceutical activity in the face of viral evolution.

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. COVID-19 persists and continues to impact patients, notably those who are immunocompromised, and combating this disease will require for years to come a variety of prevention and treatment options with demonstrated efficacy and safety. By leveraging our capabilities, which we have developed through our experience with adintrevimab and pemivibart and over five years in the COVID-19 space, we aim to develop mAbs that could be used in prevention or treatment of serious viral infectious diseases, starting with COVID-19 and expanding into other high-need indications, such as respiratory syncytial virus ("RSV") and measles.

On March 22, 2024, we received emergency use authorization ("EUA") from the U.S. Food and Drug Administration ("FDA") for PEMGARDA injection, for intravenous ("IV") 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.

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 Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

In January 2024, we nominated VYD2311, a next generation mAb candidate for COVID-19, as a drug candidate. VYD2311 is a mAb with high *in vitro* neutralization potency shown against prominent SARS-CoV-2 variants tested to date. In September 2024, we announced dosing of the first participants in a Phase 1/2 clinical trial of VYD2311. The Phase 1/2 randomized, blinded, placebo-controlled clinical trial evaluated escalating dosing as well as safety, tolerability, pharmacokinetics and immunogenicity of VYD2311 in healthy trial participants. The Phase 1/2 clinical trial was conducted in Australia and evaluated multiple dose levels of VYD2311 through various routes of administration, including exploration of intramuscular ("IM") administration and subcutaneous administration, which are designed to be more healthcare system- and patient-friendly than IV administration. In June 2025, we announced positive full Phase 1/2 clinical data for VYD2311 for both safety and pharmacokinetics. Like pemivibart, VYD2311 was engineered from adintrevimab, our investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 2/3 clinical trials for both the prevention and treatment of COVID-19.

In August 2025, we announced alignment with advice from the FDA on a compact and, therefore, rapid pathway to potential Biologics License Application ("BLA") approval for VYD2311 for the prevention of COVID-19. As part of Type C meeting feedback, the FDA advised that a single, randomized, placebo-controlled trial evaluating mAb efficacy in prevention of RT-PCR-confirmed symptomatic COVID-19 disease events could support a BLA submission for VYD2311 for the prevention of COVID-19 in a broad population of Americans (12 years of age and older, weighing at least 40kg), including immunocompromised people, subject to agreement on safety database size and pending full protocol review. In October 2025, we announced that the FDA cleared our Investigational New Drug ("IND") application for VYD2311 and provided feedback to advance our REVOLUTION clinical program, which is our development program for VYD2311. The REVOLUTION clinical program includes two clinical trials, DECLARATION and LIBERTY. In December 2025, we initiated DECLARATION, which is a Phase 3 randomized, triple-blind, placebo-controlled clinical trial to evaluate VYD2311 safety and efficacy in prevention of symptomatic, RT-PCR-confirmed COVID-19 at three months, with either a single dose or monthly doses of VYD2311, each administered via IM injection, compared to placebo. DECLARATION is designed to support potential BLA submission, with top-line data anticipated in mid-2026. In February 2026, we announced alignment with the FDA on LIBERTY, which is designed as a Phase 3, randomized, double-blind clinical trial to evaluate the

safety, serum virus neutralizing antibody responses, and pharmacokinetics of (1) VYD2311, (2) an mRNA COVID vaccine, and (3) co-administered VYD2311 with an mRNA COVID vaccine. The FDA has granted "Fast Track" designation for VYD2311 for the prevention of COVID-19 in individuals with underlying risk factors for progression to severe disease. Fast Track designation is a process designed to facilitate the development and expedite the regulatory review of drugs to treat serious conditions and fill an unmet medical need, including eligibility for priority review and rolling review of BLA submissions, if specified criteria are met.

In July 2025, we announced that we had formed the SPEAR (Spike Protein Elimination and Recovery) Study Group with leading investigators to structure and guide anticipated clinical trials evaluating the effects of broadly neutralizing anti-SARS-CoV-2 spike protein mAb therapy in people suffering from Long COVID or Post-Vaccination Syndrome ("PVS"). The SPEAR Study Group intends to launch multi-center translational clinical research on Long COVID and PVS using next-generation antibodies like our investigational mAb candidate VYD2311.

We engage in active SARS-CoV-2 variant monitoring of antiviral activity as part of our ongoing industrial virology effort, which leverages a consistent, high-quality, independent, third-party pseudoviral system that routinely tests authentic Invivyd-produced molecules and is supported by structure-based analytics. In September 2024, we announced continued neutralizing activity of PEMGARDA against SARS-CoV-2 variants KP.3.1.1 and LB.1 and attractive neutralization potency of VYD2311, our next generation mAb candidate for COVID-19, against the same contemporary viruses, and we also provided an update to ongoing structural analysis showing no meaningful mutational change in the pemivibart binding site since the Omicron shift late in 2021. In January 2025, March 2025 and August 2025, we announced continued neutralizing activity of PEMGARDA and VYD2311 against dominant SARS-CoV-2 variants XEC, LP.8.1 and XFG, respectively.

In addition to our COVID-19 programs, in November 2025, we announced the selection of VBY329, a potential best-in-class mAb candidate being developed for the prevention of RSV infections in neonates, infants and children. We expect to advance VBY329 toward IND readiness in the second half of 2026. Through our proprietary technology platform, we continue to investigate additional mAbs for protection and treatment of other important infectious diseases, such as measles. We are targeting identification of a preclinical mAb candidate for treatment and prevention of measles in the first half of 2026.

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"), WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), to execute our chemistry, manufacturing and controls ("CMC") development, testing and clinical and commercial manufacturing activities. 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"), including Adimab's platform technology. 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 product candidates that could be used in prevention or treatment of serious viral infectious diseases, starting with COVID-19 and expanding into other high-need indications. In order to achieve this goal, our strategy involves execution of the following key elements:

- **Continued execution of PEMGARDA commercial launch 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 and rare diseases spaces, and we have directly hired a field sales force.
- **Advancing VYD2311 through clinical development and regulatory review.** Following FDA IND clearance and alignment on our REVOLUTION clinical program, we have initiated our Phase 3 DECLARATION clinical trial. We have also aligned with FDA on the LIBERTY clinical trial, which will evaluate comparative safety and immunology of VYD2311 versus an mRNA COVID vaccine, as well as explore the safety and immunology of co-administered VYD2311 and an mRNA COVID vaccine. The FDA has granted Fast Track

designation for VYD2311 for the prevention of COVID-19 in individuals with underlying risk factors for progression to severe disease.

- **Establishing streamlined development pathways that would allow us to efficiently introduce new 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 SARS-CoV-2 mAbs. There are precedents for streamlined development pathways in the influenza and COVID-19 vaccine spaces for leveraging existing safety and efficacy data to bridge quickly to new or modified vaccines, and there are expedited regulatory review and approval approaches that we may pursue for our product candidates, such as the FDA's accelerated approval pathway, Fast Track designation and breakthrough therapy designation.
- **Developing potential best-in-class antibody therapies across multiple virus targets.** In addition to our work in targeting SARS-CoV-2, we are using our bespoke platform to identify mAbs for other infectious diseases, including RSV and measles.
- **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 and VYD2311. We believe we have secured sufficient supply to meet demand for PEMGARDA and anticipated initial demand for VYD2311, if approved. We continue to evaluate access to capacity at WuXi Biologics and other CDMOs so we can aim to meet potential future demand for our product candidates.
- **Advancing our differentiated product candidates to address infectious diseases through internal research and collaborations.** We have built a portfolio of broadly neutralizing SARS-CoV-2 antibodies as our lead disease area of focus. We have exclusive access to Adimab's industry-leading B-cell mining, protein and antibody engineering capabilities for coronavirus 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.
- **Leveraging our team's collective expertise in development, manufacturing and commercialization to deliver future product candidates to patients.** We have assembled a leadership team composed of seasoned executives with extensive experience, including with respect to development, manufacturing and commercializing novel medicines for infectious disease. In addition to infectious disease, our leaders' combined experience spans a broad set of therapeutic areas, such as oncology, organ transplant, rare disease, orphan disease and immunology, which provides a diverse perspective and skill set to serve our patient communities. Based on our team's collective track record, we executed on the clinical, regulatory, and manufacturing plan for PEMGARDA. We expect to leverage this experience to support our anticipated follow-on programs, including VYD2311.

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

COVID-19, the disease caused by SARS-CoV-2 and its variants, gave rise to a global pandemic in 2020. SARS-CoV-2 continues to cause infections and disease. COVID-19 remains a significant global health problem. According to estimates from the World Health Organization ("WHO") as of January 2026, there have been approximately 779 million cases of laboratory-confirmed COVID-19 and 7.1 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 are authorized for the treatment of COVID-19 in the U.S. and, other than PEMGARDA, none are authorized for prevention in the U.S., due to loss of activity as new variants emerged.

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

Our approach is designed to deliver new product candidates that exert continuous pharmaceutical activity in the face of viral evolution and that can be updated quickly as necessary via our bespoke platform. 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 infectious diseases, starting with COVID-19. 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 or rapid compact outcome-directed clinical trials, to expedite drug development. Our product candidates can be tuned to improve potency, breadth of neutralization and route of administration, 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 have chosen to identify and engineer mAbs with a high potential to resist SARS-CoV-2 variant escape. We are targeting epitopes that are (1) minimally polymorphic since the emergence of Omicron variants, (2) privileged with respect to contemporary population-level immune pressure, and (3) potentially conserved across other human sarbecoviruses (such as SARS-CoV-2) that utilize angiotensin converting enzyme-2 ("ACE-2") to infect cells, providing anticipated neutralization breadth to our mAb candidates.
- **Continuous monitoring for SARS-CoV-2 variants:** We continuously maintain and improve our in-house suite of digital monitoring tools 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, such as to extend their half-lives or modify their Fc-mediated innate immune effector function.
- **Expedited path to the clinic and market:** In order to deliver new mAb products in a rapid and timely manner to patients at risk, we believe that new, expedited approaches and pathways are needed across nonclinical, clinical and CMC development. 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,

including VYD2311. 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 believe that these data should enable the application of surrogate endpoints in future development programs, an approach that was leveraged in our Phase 3 CANOPY clinical trial of pemivibart 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 our product candidates. We anticipate actively engaging with regulatory authorities in pursuit of these proposals as we advance our product candidates.

We are employing similar antibody discovery, variant monitoring, and development strategies for other antigenically variable viruses, such as RSV, measles, and others.

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 pursuant to the relevant declaration under Section 564 of the FDCA. The FDA, therefore, may continue to issue new EUAs going forward when criteria for issuance are met. Such authority 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.

Addressable Patient Populations

Pre-Exposure Prophylaxis

The FDA issued an EUA for PEMGARDA (pemivibart) in March 2024 for the pre-exposure prophylaxis of COVID-19 in certain patients with moderate-to-severe immune compromise; no other mAb therapies for prevention of COVID-19 are currently authorized. Furthermore, no other mAb therapies for the prevention of COVID-19 have been authorized by the FDA since January 2023, when the last of the previously authorized mAb therapies lost activity against then-circulating variants.

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. Vaccines for pre-exposure prophylaxis of COVID-19 have not demonstrated adequate efficacy against symptomatic disease or more significant outcomes in the immunocompromised population. This vulnerable population that is unlikely to mount an adequate response to vaccination has been left with no therapeutic options for prevention of COVID-19 outside of PEMGARDA.

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.

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 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, Long COVID, or PVS.

Pediatrics

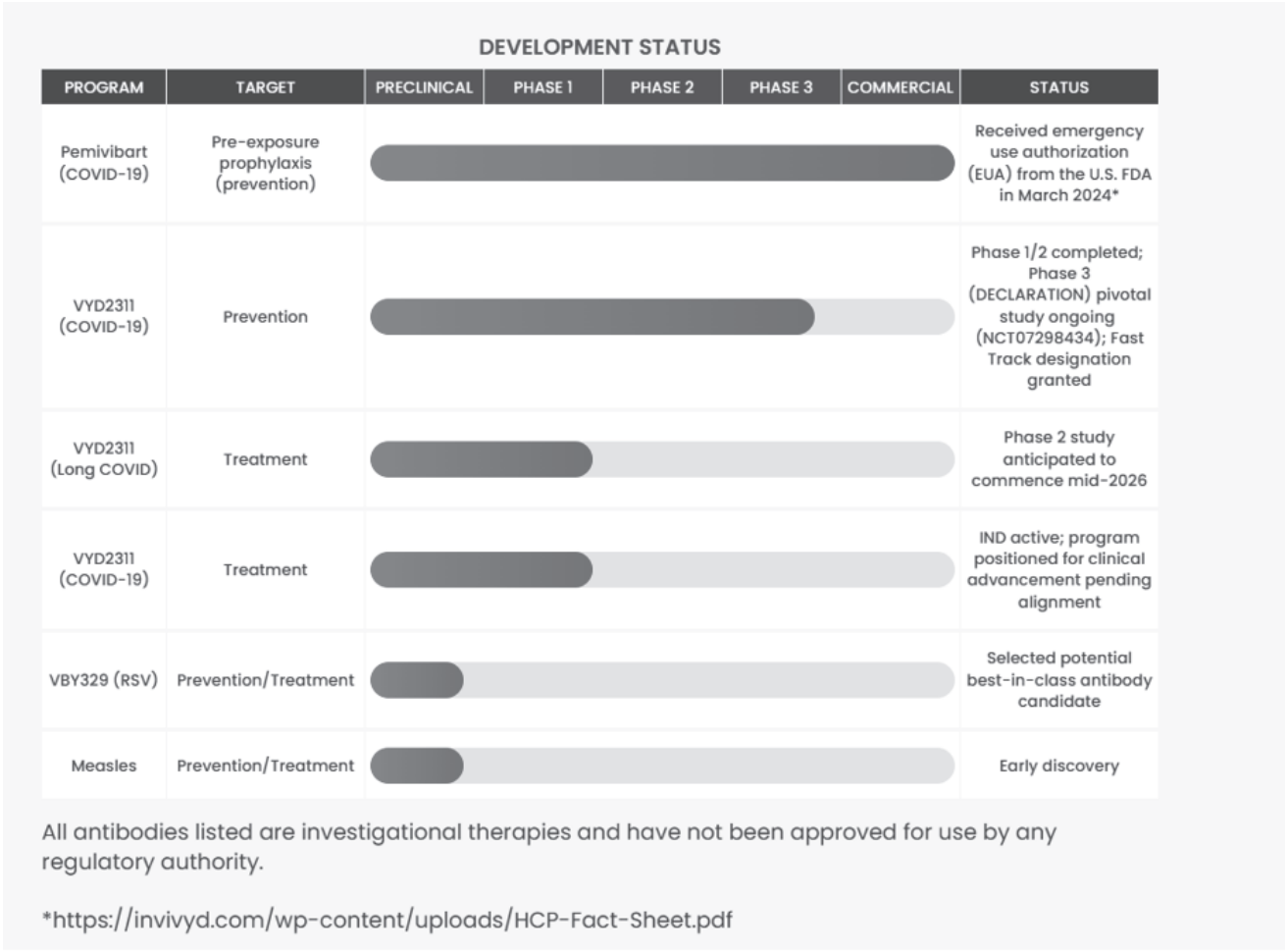
Although children are at lower risk of developing severe COVID-19 compared to adults, a subset of children experience severe disease and poor outcomes, such as multisystem inflammatory syndrome and Long COVID, and safe and effective therapies are needed to prevent disease and hospitalization in high-risk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

We are devoted to delivering protection from serious viral infectious diseases. By pairing state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering techniques, we are committed to developing a robust pipeline of product candidates designed for the prevention or treatment of serious viral infectious diseases, starting with COVID-19 and expanding into other high-need indications, such as RSV and measles.

PEMGARDA is our first mAb to receive regulatory authorization and was designed to exert continuous pharmaceutical activity in the face of viral evolution. VYD2311 is our next generation mAb candidate being developed for COVID-19 to continue to address the urgent need for new prophylactic and therapeutic options. As the SARS-CoV-2 virus evolves over time, we anticipate periodically introducing new mAb candidates, an approach that could be analogous to the periodic updates made to influenza and COVID-19 vaccines.

Beyond PEMGARDA and VYD2311, we have additional anti-SARS-CoV-2 mAb candidates in discovery and preclinical characterization. Our robust pipeline reflects our strategy to continuously discover and engineer new candidates that can respond to emerging virus variants or improve upon the biophysical properties and clinical profiles of our current antibodies. Our technology and bespoke approach to antibody discovery and development may provide a mechanism for discovery of novel mAbs to prevent or treat other serious viral infectious diseases such as RSV, measles, and beyond.



PEMGARDA

Pre-Exposure Prophylaxis

PEMGARDA® (pemivibart) is a half-life extended investigational mAb. PEMGARDA was engineered from adintrevimab, our investigational mAb that has a robust safety data package and provided evidence of clinical efficacy in global Phase 2/3 clinical trials for the prevention and treatment of COVID-19. PEMGARDA has demonstrated *in vitro* neutralizing activity against major SARS-CoV-2 variants, including JN.1, KP.3.1.1, XEC, LP.8.1 and XFG. PEMGARDA targets the SARS-CoV-2 spike protein RBD, thereby inhibiting virus attachment to the human ACE2 receptor on host cells.

PEMGARDA (pemivibart) injection (4500 mg), for IV 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/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 the treatment of COVID-19, Long COVID, or PVS, or for post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2. Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccinations, should receive COVID-19 vaccination. In individuals who have received a COVID-19 vaccine, PEMGARDA should be administered at least 2 weeks after vaccination.

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 the authorization is revoked sooner. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

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.

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. Additionally, certain SARS-CoV-2 viral variants may emerge that have substantially reduced susceptibility to PEMGARDA, and PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants.

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 reactions included systemic infusion-related reactions and hypersensitivity reactions, local infusion site reactions, and infusion site infiltration or extravasation.

We have concentrated on the healthcare practitioners and institutions who specialize in hematology, oncology, rheumatology and transplant, serving 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, and we have directly hired a field sales force.

Treatment

In February 2025, the FDA declined our request to expand the existing EUA for PEMGARDA to cover treatment of mild-to-moderate COVID-19 in adults and adolescents who have moderate-to-severe immune compromise due to certain medical conditions such as cancer and organ transplant, and for whom alternative COVID-19 treatment options are not

accessible or clinically appropriate. The existing EUA for PEMGARDA covering pre-exposure prophylaxis of COVID-19 in certain immunocompromised patients remains in effect.

VYD2311

VYD2311 is a novel mAb candidate being developed for COVID-19 to continue to address the urgent need for new prophylactic and therapeutic options. The pharmacokinetic profile and antiviral potency of VYD2311 may offer the ability to deliver clinically meaningful titer levels through more healthcare system- and patient-friendly means such as an IM route of administration. In October 2025, we announced that the FDA cleared our IND application for VYD2311 and provided feedback to advance our REVOLUTION clinical program, which is our development program for VYD2311 comprising two clinical trials, DECLARATION and LIBERTY. DECLARATION is a Phase 3 randomized, triple-blind, placebo-controlled clinical trial to evaluate VYD2311 safety and efficacy in prevention of symptomatic, RT-PCR-confirmed COVID-19 at three months, with either a single dose or monthly doses of VYD2311, each administered via IM injection, compared to placebo. DECLARATION is designed to support potential BLA submission, with top-line data anticipated in mid-2026. In February 2026, we announced alignment with the FDA on LIBERTY, which is designed as a Phase 3, randomized, double-blind clinical trial to evaluate the safety, serum virus neutralizing antibody responses, and pharmacokinetics of (1) VYD2311, (2) an mRNA COVID vaccine, and (3) co-administered VYD2311 with an mRNA COVID vaccine. The FDA has granted "Fast Track" designation for VYD2311 for the prevention of COVID-19 in individuals with underlying risk factors for progression to severe disease.

VYD2311 was engineered using our proprietary integrated technology platform and is the product of serial molecular evolution designed to generate an antibody optimized for neutralizing contemporary virus lineages. VYD2311 leverages the same antibody backbone as pemivibart, our investigational mAb granted EUA in the U.S. for the pre-exposure prophylaxis of COVID-19 in certain immunocompromised patients, and adintrevimab, our investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 2/3 clinical trials for the prevention and treatment of COVID-19.

Manufacturing Strategy

We do not currently own or operate any manufacturing facilities, and we have invested significant resources to develop commercial-scale manufacturing in partnership with our sole contract manufacturing partner for COVID-19 product candidates, 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 commercial cell line, fed-batch suspension cell culture and a chromatography column-based purification process. WuXi Biologics 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. We may terminate the master services agreements effective immediately in connection with certain new or existing U.S. laws and regulations, in accordance with the terms of the agreements. With advance notice, we may also terminate the master services agreements for convenience. 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 significant resources to the manufacture of PEMGARDA and VYD2311, and we believe we have secured sufficient supply to meet demand for PEMGARDA and anticipated initial demand for VYD2311, if approved.

Foreign contract manufacturing organizations, including WuXi Biologics, may become subject to U.S. legislation, such as the National Defense Authorization Act, investigations, sanctions, trade restrictions, tariffs, and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay or impact clinical trials, delay procurement of commercial supply, or impact potential U.S. government contracting opportunities. 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, VYD2311, and future clinical product candidates.

Distribution Strategy

Unlike previous EUAs for COVID-19, where products were available via an advance purchase agreement with the U.S. federal government, PEMGARDA follows a traditional commercial distribution model in which end customers either purchase the product directly from third-party specialty distributors or for a small number of infusion centers, healthcare provider and provider institutions, directly with us. The product is then shipped directly to the various sites of care, including provider institutions, infusion centers and clinics that bill health insurance plans for the product.

We have entered a third-party logistics distribution agreement (the "3PL Agreement") with a distribution agent (the "3PL Agent") that distributes our product to our end customers. The 3PL Agent provides us with services that include storage, distribution, processing product returns, customer service support, logistics support, electronic data interface and system access support.

During the year ended December 31, 2025, our net product revenue was generated from sales to third-party specialty distributors and directly to a small number of infusion centers, healthcare providers and provider institutions in the U.S. Three specialty distributors accounted for 46%, 23% and 17% of total gross sales for the year ended December 31, 2025.

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 (the "Adimab Assignment Agreement") 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—Adimab Assignment Agreement." In May 2021, we entered into a collaboration agreement with Adimab (as amended in November 2022 and September 2023, the "Adimab Collaboration Agreement") 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—Adimab Collaboration Agreement." In addition, in September 2022, we entered into a platform transfer agreement with Adimab (the "Adimab Platform Transfer Agreement"). Under the Adimab 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 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, 2025, we 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"). While reserving all rights under the Adimab Assignment Agreement and the applicable law, through December 31, 2025, we made aggregate royalty payments of $2.5 million.

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, 2025, we had made aggregate payments of $16.2 million to Adimab under the Adimab Assignment Agreement, inclusive of the aforementioned milestone and royalty payments. As of December 31, 2025, $0.7 million was accrued under the Adimab Assignment Agreement.

Adimab Collaboration Agreement

In May 2021, we entered into 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 experienced a change of control after the third anniversary of the Adimab Collaboration Agreement or (ii) Adimab owned 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. Effective January 2024, we became obligated to pay Adimab a quarterly fee of $0.6 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.

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, 2025, we had made aggregate payments of $22.8 million to Adimab under the Adimab Collaboration Agreement.

Adimab Platform Transfer Agreement

In September 2022 (the "Adimab Platform Transfer Agreement Effective Date"), we entered into 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, 2025, we had made aggregate payments of $9.0 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 renewed for subsequent periods, until terminated in accordance with its terms. The PHP MSA was terminated effective July 2024. 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 contained 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. Tamsin Berry, a member of our board of directors, is a Limited Partner of PHP.

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). As of December 31, 2025, no portion of the PHP Warrant had vested.

Cell Line License Agreement with WuXi Biologics

We are party to a Cell Line License Agreement with WuXi Biologics, entered into as of December 2, 2020, as amended in February 2023, March 2024 and March 2026. Through December 31, 2025, we made aggregate payments of $0.2 million to WuXi Biologics under the Cell Line License Agreement. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Contractual Obligations and Commitments" and "—Other Commitments."

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, competition may come 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 potential 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, as well as other therapeutic areas in which we are actively performing research and discovery activities, including RSV and measles. Companies that have active COVID-19 antibody-based programs include, but may not be limited to, AstraZeneca plc and Roche Pharmaceuticals. 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).

Aside from pemivibart, which is authorized under EUA, there are no other currently authorized or approved mAbs for COVID-19 prevention in the U.S. Actemra® (Genentech) is utilized for the treatment of COVID in hospitalized adults and children requiring oxygen/ventilation. Alternative COVID-19 prevention competition exists from mRNA vaccine manufacturers Moderna and Pfizer-BioNTech, as well as protein subunit vaccine from Novavax (authorized for people 12 years and older).

Current RSV prevention options for adults are limited to protein-based vaccines from Pfizer and GSK and an mRNA vaccine from Moderna. Currently there is a mAb, Beyfortus® (nirsevimab), offered jointly by AstraZeneca and Sanofi authorized for use by infants and children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. In addition, Enflonsia™ (clesrovimab) is a mAb produced by Merck for passive immunization to prevent serious RSV lower respiratory tract disease in newborns and infants entering their first RSV season.

Existing options for measles prevention are limited to MMR (Measles, Mumps, Rubella) vaccines produced by Merck and GSK; there are no current measles mAb products authorized or approved for use.

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 February 15, 2026, 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, Canada, China, Europe, and Mexico. 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 February 15, 2026, we own another patent family for which we have one pending U.S. non-provisional patent application. This patent family is directed to formulations and methods of use for ADG20 (adintrevimab). Any additional U.S. non-provisional 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 February 15, 2026, we own a patent family directed to additional broadly neutralizing anti-coronavirus antibodies, combination therapies, and uses thereof, for which we have one pending U.S. non-provisional patent application, and foreign patent applications in Europe and Taiwan. These patent applications and any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon such applications, if issued, are expected to expire in 2043, without taking into account any possible patent term adjustment or extension.

As of February 15, 2026, we own a patent family directed to additional broadly neutralizing anti-coronavirus antibodies, including VYD222, as well as combination therapies, and uses thereof, for which we have one pending U.S. non-provisional patent application and foreign patent applications in Australia, Canada, and Europe. These patent applications and any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon these patent applications, if issued, are expected to expire in 2043, without taking into account any possible patent term adjustment or extension.

As of February 15, 2026, we own a patent family directed to additional broadly neutralizing anti-coronavirus antibodies, including VYD2311, combination therapies, and uses thereof, for which we have a pending PCT application and a U.S. non-provisional patent application. Any additional U.S. non-provisional patent applications or foreign patent applications timely filed based upon such patent applications, if issued, are expected to expire in 2045, without taking into account any possible patent term adjustment or extension.

As of February 15, 2026, we own a patent family directed to additional broadly neutralizing anti-RSV antibodies, including VBY329, combination therapies, and uses thereof for which we have a pending U.S. provisional patent application. Any U.S. non-provisional patent applications or foreign patent applications timely filed based upon the U.S. provisional patent application, if issued, are expected to expire in 2046, 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 February 15, 2026, 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 U.S., and while many are still pending, a number of registrations have been issued in the U.S., Australia, China, the European Union, Japan, New Zealand, Norway, Switzerland, and the 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 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 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, and may also include animal studies to assess the potential safety and activity of the product candidate. The conduct of the nonclinical tests

must comply with applicable 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. Such investigators are generally physicians who are 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 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 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, nonclinical 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 significant user fees. 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 may be filed under protest or 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 current FDA performance goals provide that the FDA should review and act on 90% of standard new molecular entity New Drug Applications and original BLAs within ten months after the 60-day filing date. The FDA may miss or extend these goal actions dates under certain circumstances, including if there is a major amendment to the

application. 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. However, even if priority review is awarded, the FDA may miss or extend the action date.

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, which is 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 approved conditions of use may be significantly limited to specific diseases and dosages, 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 pursuant to the relevant declaration under Section 564 of the FDCA. The FDA therefore may continue to issue new EUAs going forward when criteria for issuance are met. Such authority 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"), the FTC Health Breach Notification Rule, 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 (the "GDPR"), the United Kingdom's General Data Protection Regulation, the United Kingdom's Data Protection Act 2018, the United Kingdom's Data (Use and Access) Act 2025 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, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and the regulations promulgated thereunder (collectively, "HIPAA"). 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 criminal 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, and subject to other civil and/or criminal penalties if we obtain, use, or disclose information in a manner not permitted by other privacy and data security and consumer protection laws. We rely on third party vendors and services to support various aspects of our business operations; however, these third parties may pose risks related to data security compliance and contractual obligations. A breach or failure by a third party to adequately protect our data could have adverse consequences for our business and reputation.

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. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. Enforcement by the FTC under the FTC Act and Health Breach Notification Rule can result in civil penalties or enforcement actions.

Moreover, as a result of the broad scale release and availability of Artificial Intelligence ("AI") technologies such as generative AI, there is a global trend towards more regulation (e.g., the European Union AI Act and AI laws passed by U.S. states) to ensure the ethical use, privacy, and security of AI and the data that it processes. Compliance with such laws will likely be an increasing and substantial cost in the future.

Expedited Review and Approval Programs

The FDA has various approaches, including Fast Track designation, priority review, accelerated approval and breakthrough therapy designation, that are intended to expedite the process for the development and/or 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. These designations provide benefits such as early regulatory interactions, rolling reviews, shorter approval timelines, and shorter review timelines, potentially accelerating patient access to innovative therapies.

Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. 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.

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 product may receive a breakthrough therapy designation if it is 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 may also be eligible for Fast Track benefits (including priority review) and use of the accelerated approval pathway. 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.

Prior to approval, each drug marketed in the U.S. must go through a detailed FDA review process. In 1992, under PDUFA, the FDA agreed to specific goals for improving the marketing application review time and set forth two review tracks – standard review and priority 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 ten months from the 60-day filing date under current PDUFA performance goals. Products that receive Fast Track designation are eligible to receive a priority review if the relevant criteria are met.

Mindful of the fact that it may take an extended period of time to measure a drug's intended clinical benefit, in 1992 FDA instituted the accelerated approval regulations, and this pathway was codified in the FDCA in 2012. 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 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 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.

A biological product can qualify for multiple expedited pathways and designations if it meets the respective criteria. 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 are not intended to lower 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, a clinical trial must be authorized by the competent authority of each country where the trial is to be conducted, and be subject to ethical review by the relevant national ethics committee(s). Clinical trials are governed by the Clinical Trials Regulation (Regulation (EU) No 536/2014) (the "CTR"), which came into effect on January 31, 2022, and is applicable in all the European Union Member States, as well as in Iceland, Liechtenstein and Norway. The CTR repealed the previous Clinical Trials Directive (Directive 2001/20/EC) (the "CTD"). Under the CTR, sponsors submit one application via an online platform known as the Clinical Trials Information System ("CTIS") for authorization to run a clinical trial in one or more European Union countries. While a part of the application assessment is done by the country designated as the Reporting Member State, the decision on the authorization of clinical trials, however, remains a responsibility of each country. The use of the CTIS is mandatory for clinical trial applications ("CTAs") submitted on or after January 31, 2023. Clinical trials authorized under the CTD before January 31, 2023 could continue without any discontinuation or hold requirements. However, beginning on January 31, 2025, such clinical trials had to be transitioned to the CTR framework, including being subject to the requirement to record information on the trials in the CTIS.

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 trials are conducted in accordance with cGCP, applicable regulatory requirements and applicable ethical principles.

To obtain regulatory approval of a biological medicinal product under the European Union regulatory system, we would be required to 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, as well as 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 explanations are to be provided by the applicant in response to questions posed by the CHMP. A request for accelerated assessment might be granted by the CHMP in exceptional cases when a medicinal product is expected to be of a major public health interest. There is no single definition of what constitutes a major public health interest. This should be justified by the applicant and assessed by the CHMP on a case by case basis. Typically, the justification should include the major benefits expected and demonstrate that the medicinal

product introduces new methods of therapy or improves on existing methods, thereby addressing to a significant extent public health unmet needs. If the CHMP accepts to review a medicinal product under the accelerated assessment procedure, 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 on whether or not 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 such as those developed by means of hybridoma and monoclonal antibody methods, 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 patients' health at European Union level.

Unlike the centralized authorization procedure, the decentralized marketing authorization procedure requires a separate application to, and leads to separate authorizations 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. One of the relevant European Union Member States is selected by the applicant as the Reference Member State and prepares a draft assessment report, a draft Summary of Product Characteristics ("SmPC"), and a draft of the labeling and package leaflet. The other concerned 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 will be referred to a coordination group and could thereafter be referred to the EMA, which could result in a decision from the European Commission.

The mutual recognition procedure is used in order to obtain marketing authorizations in several European Union Member States where the medicinal product in question has already received a marketing authorization in any European Union Member State at the time of application. 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, during the applicable period, applicants and regulatory authorities in the European Union from referencing the innovator's data to apply for or 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 authorized, 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 ten 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 determine the conditions in which a medicinal product may be authorized to treat the pediatric population. All applications for marketing authorization for new medicinal products have to include the results of studies as described in an agreed PIP, unless the medicinal product 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 medicinal product that is already authorized and covered by intellectual property rights. Several rewards and incentives for the development of

pediatric medicinal products are available in the European Union. Medicinal products 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 medicinal products. Medicinal products developed specifically for children that are not protected by a patent or supplementary protection certificate are eligible for a pediatric-use marketing authorization, which if granted, provides ten years of market protection.

The European Union pharmaceutical legislation is currently under review. On April 26, 2023, the European Commission published its proposal to revise the European Union pharmaceutical legislation (the "EU Pharma Package"), consisting of a new Directive and a new Regulation, which would revise and replace the existing general pharmaceutical legislation (Regulation 726/2004 and Directive 2001/83/EC) and the legislation on medicinal products for pediatric use and on orphan medicinal products (Regulation 1901/2006 and Regulation 141/2000, respectively). In December 2025, the European Parliament and the Council of the European Union reached a provisional agreement on the EU Pharma Package. Among others, this provisional agreement contemplates certain changes to regulatory exclusivity periods. The regulatory data protection period is proposed to be kept at eight years, with one additional year of regulatory market protection. Pharmaceutical companies would be eligible for additional one-year periods of regulatory market protection: (i) if the particular product addresses an unmet medical need; (ii) if the particular product contains a new active substance, it meets a combination of conditions on comparative clinical trials carried out in several European Union Member States, and the application for marketing authorization occurs within 90 days after the submission of the first MAA outside the European Union; or (iii) if the company obtains an authorization for one or more new therapeutic indications that bring a significant clinical benefit in comparison with existing therapies. The provisional agreement sets a cap of 11 years on the combined regulatory market protection period. The timeframe for the evaluation of an MAA is expected to be reduced to 180 days (from the current 210 days). The provisional agreement is still subject to the formal approval by the European Parliament and the Council of the European Union and subsequent publication in the Official Journal of the European Union. After a transition period, the new legislation is expected to apply beginning in mid-2028.

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.

Under the Human Medicines (Amendment etc.) (EU Exit) Regulations 2019, 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 Trade and Cooperation Agreement ("TCA"), 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 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, from January 1, 2025, when the Windsor Framework took effect, a single marketing authorization now covers the whole of the United Kingdom and has replaced previous separate licenses for Great Britain and Northern Ireland. Marketing authorizations obtained under the European Union centralized authorization procedure are no longer valid in Northern Ireland, and have been converted into a United Kingdom-wide marketing authorization. The Windsor Framework has also introduced United Kingdom-only labelling changes for all medicines placed on the United Kingdom market and disapplied the European Union Falsified Medicines Directive in Northern Ireland. The United Kingdom also has an 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.

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, 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 and Medicaid programs, 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. 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 allowing companies to fix

their own prices with direct or indirect controls on the profitability of the company placing the medicinal product 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.

The European Union's HTA Regulation was adopted on December 13, 2021, entered into force on January 11, 2022 and became effective 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 and sets the basis for permanent and sustainable cooperation at the European Union level for joint clinical assessments. 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 an individual or the purchase, order, lease, or arranging for or recommending purchasing, leasing, or ordering any 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 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 medicinal 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 authorized product's SmPC. 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, including those by private payors;
- HIPAA imposes 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. 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 rebate liability for manufacturers that participate in the Medicaid Drug Rebate Program and expanded the 340B program. 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. The Inflation Reduction Act of 2022 ("IRA") ended the Part D coverage cap discount program, which was first enacted as part of the ACA, under which manufacturers agreed to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during the coverage gap period, and replaced it with a new Part D Manufacturer Discount Program that began in 2025. Under this Manufacturer Discount Program, manufacturers are generally required to provide a 10% discount on a covered Part D drug where a beneficiary is in the initial phase of Part D coverage and a 20% discount where a beneficiary is in the catastrophic phase of Part D coverage.

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. Sequestration is currently set at 2% through 2033. The American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap, previously 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, established a Medicare Part B inflation rebate scheme, under which, generally speaking, manufacturers owe rebates if a reportable average sales price of an eligible Part B rebatable drug, not including certain vaccines, increases faster than the pace of inflation. The IRA also established a Medicare Part D inflation rebate scheme, under which, generally speaking, manufacturers owe rebates if a reported annualized average manufacturer price ("AMP") of

an eligible Part D rebatable drug increases faster than the pace of inflation. Failure to timely pay a Part B or Part D inflation rebate for a product subject to these programs is subject to a civil monetary penalty. The IRA also created a drug price negotiation program under which the prices for Medicare units of certain FDA approved or licensed 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. 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 made 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 for an applicable drug that could negatively affect the profitability of our product candidates. The IRA also prohibited 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 pricing or bundled payment models.

On July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law. The OBBBA is projected to decrease federal health care spending by approximately $1 trillion by reducing Medicaid spending and enrollment and making changes to federal Medicare spending. The law also made changes to ACA marketplace enrollment that are projected to decrease the number of individuals with marketplace coverage. It is unclear if these changes will impact demand for our products, once authorized or approved.

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 Medicaid and reform government program reimbursement methodologies for pharmaceutical products. At the federal level, the government has shown substantial interest in taking a variety of measures aimed at lowering U.S. prescription drug prices to align with the lowest prices available for the same drugs in comparable developed nations (so called "most favored nation" pricing). As another example of federal activity in this area, 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. Additionally, some individual states have begun establishing Prescription Drug Affordability Boards to review high-cost drugs and, in some cases, set upper payment limits.

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.

Employees and Human Capital Resources

As of February 1, 2026, we had 122 employees, all of which were full-time employees. Approximately 16 of our employees have Ph.D. or M.D. degrees and 35 of our employees are engaged in research and development activities. We have a hybrid workforce, with approximately 34% of our employees based in Massachusetts, 9% based in Connecticut, 7% based in California, 7% based in New Jersey, and the remaining 43% 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 New Haven, Connecticut, our laboratory in Newton, Massachusetts and remotely.

We rent office space in an office building in New Haven, Connecticut 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 future 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, 2025. 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, 2025, 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 and are highly dependent on the commercial success of our only authorized product, PEMGARDA, for the foreseeable future, until VYD2311 or any other product candidate is authorized or approved and successfully commercialized, if ever. We may not 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 $52.5 million and $169.9 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $954.5 million. Since our inception, we have financed our operations primarily with net proceeds from several public and private offerings of our capital stock. After receiving EUA in March 2024, we have also funded our operations from sales of PEMGARDA, but have no other products authorized or approved for commercialization.

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:

- continue to commercialize PEMGARDA, as well as advance development of our other product candidates, such as VBY329;
- advance the development of VYD2311 and prepare for its potential commercial launch, if approved;
- initiate and conduct clinical trials of our product candidates, including our REVOLUTION clinical program for VYD2311;
- develop product candidates in new indications or patient populations;
- advance our preclinical and discovery programs, such as RSV and measles, 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.

Our ability to 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 will remain highly dependent on the commercial success of our only authorized product, PEMGARDA, for the foreseeable future, until VYD2311 or any other product candidate is authorized or approved and successfully commercialized, if ever.

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. 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 limited experience with 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 to date, we have received regulatory authorization for only one product candidate, PEMGARDA, which received an EUA from the FDA in March 2024 for pre-exposure prophylaxis of COVID-19 in certain immunocompromised patients. It is uncertain as to if or when we may be successful in expanding the authorized use of PEMGARDA, if ever. Our operations to date have been largely focused on organizing and staffing, building an intellectual property portfolio, business planning, conducting research and development, regulatory activities, establishing and executing arrangements for third-party manufacturing of our product candidates, commercializing PEMGARDA, and capital raising. Our recent focus has been and will continue to be supporting the commercialization of PEMGARDA, advancing VYD2311 as our next generation mAb candidate for COVID-19, and preparing for the potential commercial launch of VYD2311, if approved. Furthermore, while we continue to advance our BLA-enabling clinical program for VYD2311, it is uncertain as to if or when we may submit such BLA for VYD2311 or an application for regulatory authorization or approval for any other product candidate, and we may not be successful in receiving any such additional regulatory authorization or 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 or commercial history. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors.

We will 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 support our continuing operations and pursue our growth strategy. If we are unable to secure and access 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 advance VYD2311 as our next generation mAb candidate for COVID-19 and otherwise develop our product candidate pipeline. 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 to expand the authorized use of PEMGARDA or if we obtain regulatory approval of VYD2311 or regulatory authorization or approval for another product candidate that we develop 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 PEMGARDA or sales of any future authorized or approved product, we expect to finance our operations through a combination of equity offerings, government or private-

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

As of December 31, 2025, we had cash and cash equivalents of $226.7 million. 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, such as VYD2311 and VBY329;
- 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;
- 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 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 expect to require additional capital to achieve our business objectives. In December 2023, we entered into a Controlled Equity Offering℠ 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 from time to time through Cantor in transactions deemed to be "at the market offerings", as defined in Rule 415 under the Securities Act of 1933. 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 tariff uncertainty, 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, we expect to finance our operations through a combination of equity offerings, government or private-party grants, debt financings or other capital sources, such as collaborations with other companies, strategic alliances or licensing arrangements. Aside from our milestone-based Term Facility (as defined below), 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. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

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.

Our failure to comply with the covenants or other terms of our Loan Agreement, including as a result of events beyond our control, could result in a default under the Loan Agreement that could materially and adversely affect the ongoing viability of our business.

On April 18, 2025 (the "Closing Date"), we entered into that certain Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, as lender (the "Lender"), that provides for a senior secured term loan facility in an aggregate principal amount of up to $30 million (the "Term Facility") consisting of: (a) Term A Loans in an aggregate principal amount of up to $10 million, which shall be available to be drawn from and after August 15, 2025 through December 31, 2026 upon compliance with certain financial covenants and conditions; (b) Term B Loans in an aggregate principal amount of up to $10 million, which shall be available to be drawn during the period commencing on the date of the achievement of certain net product revenue milestones and ending on June 30, 2027; and (c) Term C Loans in an aggregate principal amount of up to $10 million, which shall be available to be drawn during the period commencing on the date of the achievement of certain net product revenue milestones and ending on June 30, 2027 (collectively, the "Term Loans").

The Term Loans (i) are due and payable on March 1, 2029 (the "Maturity Date") and (ii) bear interest that is payable monthly (commencing with the month in which any loans are funded under the Term Facility) in arrears at a per annum rate (subject to increase during an Event of Default (as defined in the Loan Agreement)) equal to the greater of (x) the Wall Street Journal prime rate minus 0.25% (subject to a 9.00% cap) and (y) 6.00%. Commencing on April 1, 2027 (which date may be extended to April 1, 2028 upon the achievement of certain net product revenue milestones (the "Interest-Only Period Extension")), we will be required to repay the principal of the Term Facility in 24 consecutive equal monthly installments (or, in the case of the Interest-Only Period Extension, 12 consecutive equal monthly installments). At maturity, or if earlier prepaid, we will also be required to pay a final payment fee equal to 4.50% of the aggregate principal amount of the Term Loans advanced under the Term Facility. The Loan Agreement provides for an unused term loan commitment fee equal to 1.00% of the Term Facility upon the earliest to occur of (1) July 1, 2027, (2) the occurrence of an Event of Default and (3) the termination of the Loan Agreement; provided, that such fee will be waived by the Lender in the event that we have requested and the Lender has funded any loans under the Term Facility prior to such date.

Our obligations under the Loan Agreement are secured by a pledge of substantially all of our assets, excluding intellectual property. Certain of our future subsidiaries, if any, will be required to become co-borrowers under the Loan Agreement or guarantee our obligations under the Loan Agreement. In addition, such subsidiaries will be required to pledge substantially all of their assets, excluding intellectual property, to secure our obligations under the Loan Agreement. None of our subsidiaries in existence as of the Closing Date were required to be co-borrowers or guarantors or to so pledge their assets.

The Loan Agreement contains affirmative and negative covenants, including limitations on our ability and our subsidiaries' abilities, among other things, to incur additional debt, grant or permit additional liens, make investments and acquisitions, merge or consolidate with others, dispose of assets, pay dividends and distributions, enter into affiliate

transactions and change our line of business, in each case, subject to certain exceptions. In addition, the Loan Agreement contains quarterly financial covenants requiring us to maintain (a) commencing at the end of the quarter following the advance of any loans under the Term Facility, a certain amount of minimum net product revenue and (b) commencing with the quarter ending December 31, 2025, either (i) a certain amount of minimum EBITDA or (ii) minimum unrestricted cash and cash equivalents in an amount equal to or greater than the greater of (x) an amount equal to the sum of our six-month Cash Burn (as defined in the Loan Agreement) and the aggregate amount of loans outstanding under the Term Facility and (y) the aggregate amount of loans outstanding under the Term Facility multiplied by two (the "Minimum Cash Threshold"). In addition, if we no longer maintain active sales of a product in the U.S., we will be required to maintain the Minimum Cash Threshold at all times.

The Loan Agreement also includes Events of Default, in certain cases subject to customary periods to cure, following which the Lender may accelerate all amounts outstanding under the Term Facility and stop advancing money or extending credit. For example, the Lender may elect to accelerate the repayment of all unpaid principal of the Term Loans, accrued interest and other amounts owed under the Loan Agreement upon the occurrence of certain Events of Default, including, among other things:

- our default in a payment obligation under the Loan Agreement;
- our breach of the restrictive covenants or other terms of the Loan Agreement;
- the occurrence of a material adverse change in our business operations or condition (financial or otherwise);
- a material impairment in the perfection or priority of the Lender's lien in the collateral specified in the Loan Agreement;
- certain specified judgment defaults and cross-defaults to other debt agreements;
- the consummation of a specified change of control transaction; and
- certain specified insolvency and bankruptcy-related events.

If we draw down any of the Term Loans under the Term Facility, our assets or cash flow may not be sufficient to fully repay our obligations under the Loan Agreement if the obligations thereunder are accelerated upon any Events of Default. Further, if we are unable to repay, refinance or restructure our obligations under the Loan Agreement, the Lender could proceed to protect and enforce their rights under the Loan Agreement by exercising such remedies (including foreclosure on the assets securing our obligations under the Loan Agreement) as are available to the Lender and in respect thereof under applicable law, either by suit in equity or by action at law, or both, whether for specific performance of any covenant or other agreement contained in the Loan Agreement or in aid of the exercise of any power granted in the Loan Agreement. The foregoing would materially and adversely affect the ongoing viability of our business.

If we are unable to satisfy certain conditions in the Loan Agreement, we will be unable to draw down the amounts of the term loan facility.

For our Loan Agreement, we must satisfy certain conditions to be eligible to draw down the Term Loans.

The Term A Loans shall be available to be drawn from and after August 15, 2025 through December 31, 2026 upon compliance with certain financial covenants, provided that we satisfy certain conditions described in the Loan Agreement. The Term B Loans shall be available to be drawn during the period commencing on the date of the achievement of certain net product revenue milestones and ending on June 30, 2027, provided that we satisfy certain conditions described in the Loan Agreement. The Term C Loans shall be available to be drawn during the period commencing on the date of the achievement of certain net product revenue milestones and ending on June 30, 2027, provided that we satisfy certain conditions described in the Loan Agreement. As of December 31, 2025, we had not satisfied certain financial covenants and conditions, including the net product revenue milestone required to be eligible to access proceeds from the Term Facility. Accordingly, as of December 31, 2025, no amounts have been drawn down under the Loan Agreement.

If we are unable to satisfy those conditions, we would not be able to draw down the respective Term Loans and may not be able to obtain alternative financing on commercially reasonable terms or at all.

Our Loan Agreement contains restrictions that limit our flexibility in operating our business.

The Loan Agreement contains various covenants that limit our ability to engage in specified types of transactions without the prior consent of the Lender, including our ability to, among other things:

- convey, sell, lease, transfer, assign, or otherwise dispose of our assets;
- engage in any business other than the businesses currently engaged in by us or reasonably related thereto;

- liquidate or dissolve;
- merge or consolidate;
- acquire all or substantially all of the stock, partnership, membership, or other ownership interest or other equity securities or property of another entity;
- create, incur or assume additional indebtedness;
- encumber or permit liens on certain of our assets;
- make restricted payments, including paying dividends on, repurchasing or making distributions with respect to our common stock, subject to certain exceptions;
- make specified investments; and
- enter into certain transactions with our affiliates.

The covenants in our Loan Agreement may limit our ability to take certain actions that may be in our long-term best interests. In the event that we breach one or more covenants, the Lender may choose to declare an Event of Default and require that we immediately repay any amounts outstanding under the Loan Agreement, plus fees, terminate the Lender's commitments to fund any undrawn Term Loans and foreclose on the collateral granted to them to secure the obligations under the Loan Agreement. Such repayment could have a material adverse effect on our business, operating results and financial condition.

To service our indebtedness, as applicable, we will require a significant amount of cash and our ability to generate cash depends on many factors beyond our control.

Our ability to make cash payments on our indebtedness, as applicable, will depend on our ability to generate significant operating cash flow in the future. This ability is, to a significant extent, subject to general economic, financial, competitive, legislative, regulatory and other factors, that will be beyond our control. In addition, our business may not generate sufficient cash flow from operations to enable us to pay our indebtedness or to fund our other liquidity needs. In any such circumstance, we may need to refinance all or a portion of our indebtedness, on or before maturity. We may not be able to refinance any indebtedness on commercially reasonable terms or at all. If we cannot service our indebtedness, as applicable, we may have to take actions such as selling assets, seeking additional equity or reducing or delaying capital expenditures, strategic acquisitions and investments. Any such action, if necessary, may not be effected on commercially reasonable terms or at all. The instruments governing our indebtedness may restrict our ability to sell assets and our use of the proceeds from such sales.

Risks Related to the Development of our Product Candidates

Newly emerging and future SARS-CoV-2 variants could reduce the activity and effectiveness of mAbs for 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 causes 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 mAbs for 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 our investigational mAb adintrevimab had the potential to broadly neutralize SARS-CoV-2 and 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.

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. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%. To date, PEMGARDA has demonstrated *in vitro* neutralizing activity against major SARS-CoV-2 variants, including JN.1, KP.3.1.1, XEC, LP.8.1 and XFG. 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, which would adversely affect our commercial prospects, and our ability to generate revenues from PEMGARDA may be limited or lost.

As the SARS-CoV-2 virus evolves over time, we anticipate leveraging our integrated technology platform to periodically introduce new mAb candidates. Our platform is designed to produce new mAb candidates that provide broad *in vitro* neutralization against past and current VOCs and their sublineages and that exert continuous pharmaceutical activity in the face of viral evolution. For example, in January 2024, we nominated VYD2311, a mAb optimized for neutralization potency against SARS-CoV-2 lineages such as BA.2.86 and JN.1, as a drug candidate. However, 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 submission for regulatory authorization or approval. Further, we may not be able to address reductions in neutralization potency with adjustments to the dose or dosing frequency, and our current and future product candidates 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. These risks may significantly and adversely affect our ability to complete our clinical trials and obtain and maintain approval of and commercialize VYD2311 or any other 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. 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 substantially 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 only 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. In January 2024, we nominated VYD2311, a next generation mAb candidate for COVID-19, as a drug candidate, and in October 2025, we announced that the FDA cleared our IND application for VYD2311 and provided feedback to advance our REVOLUTION clinical program, which is our development program for VYD2311 comprising two clinical trials, DECLARATION and LIBERTY. In December 2025, we initiated DECLARATION, and in February 2026, we announced alignment with the FDA on LIBERTY, each as further described in Part I, Item 1 "Business" of this Annual Report on Form 10-K. However, we cannot be certain of the current or future development, regulatory or commercialization timelines of VYD2311. Our ability to generate revenue from VYD2311 or any of our other product candidates will depend heavily on successfully completing development, obtaining regulatory authorization or approval, obtaining manufacturing supply, capacity and expertise, and eventually commercializing such product candidates.

The success of PEMGARDA, VYD2311 or any other product candidates that we develop or otherwise may acquire will depend on many factors, including:

- whether the epitopes targeted by PEMGARDA, VYD2311 or any other COVID-19 mAb candidates remain structurally intact, and whether any such product candidates are able to demonstrate and sustain neutralizing activity against new or emerging SARS-CoV-2 variants or whether such SARS-CoV-2 variants reduce the neutralizing activity and effectiveness of such product candidates;
- 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, and the existence of any other available therapies that effectively prevent or treat COVID-19 in the populations targeted by our product candidates;
- 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 efficiently periodically introduce new mAb candidates targeting SARS-CoV-2, including willingness of regulators to utilize a correlate of protection (surrogate of clinical efficacy) to understand and quantify the relationship between COVID-19 mAbs and estimated clinical

protection for related mAbs derived from the same platform without requiring clinical assessment of every individual SARS-CoV-2 variant;

- 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 align with the FDA or other regulatory authorities as to the design or implementation of our clinical trials, and our eligibility for expedited regulatory review and approval approaches that we may pursue for our product candidates;
- our ability to align with the FDA or other regulatory authorities on the data required to support the regulatory authorization or approvals that we seek for our product candidates;
- the sufficiency of our financial and other resources to complete the necessary nonclinical studies and clinical trials, manufacture our product candidates and complete associated regulatory activities;
- our ability to establish and maintain agreements for clinical and commercial supply of our product candidates, and to successfully develop, obtain regulatory authorization or approval for, and 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 product candidates we identify in-house or acquire through collaborations;
- timely receipt of regulatory authorizations or approvals, 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;
- 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 are willing to pay out-of-pocket for such products, in the absence of such coverage or reimbursement;
- 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 for which we receive regulatory authorization or approval, which would substantially harm our business. If we do not maintain regulatory authorization for PEMGARDA or receive and maintain regulatory authorization or approval for VYD2311 or any other product candidates we develop or otherwise may acquire, we may not be able to continue our operations.

Because our COVID-19 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 COVID-19 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. Other small and large companies may be 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 are authorized for the treatment of COVID-19 and, other than PEMGARDA, none of these products are authorized for prevention of COVID-19 in the U.S., due to loss of activity as new variants emerged.

Because the use of 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. For example, the development pathways for our COVID-19 mAb candidates have evolved over time. In pursuing, and eventually obtaining, an EUA for PEMGARDA (pemivibart) 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. With respect to VYD2311, our next-generation mAb candidate for COVID-19, rather than pursuing an EUA in the U.S., we aligned with the FDA on a compact and, therefore, rapid pathway to potential BLA approval. As part of Type C meeting feedback, the FDA advised that a single, randomized, placebo-controlled trial evaluating mAb efficacy in prevention of RT-PCR-confirmed symptomatic COVID-19 disease events could support a BLA submission for VYD2311 for the prevention of COVID-19 in a broad population of Americans, and the FDA subsequently cleared our IND application and provided feedback to advance our REVOLUTION clinical program for VYD2311.

We continue to engage with the FDA with the aim of establishing expedited and replicable pathways for the authorization or approval of SARS-CoV-2 mAbs. 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, including VYD231. We seek to streamline nonclinical toxicology studies where possible, with the intention of reducing dependence on animal studies, and to leverage data to enable the application of surrogate endpoints in COVID development programs. However, there can be no assurance of the outcome of these discussions. 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. For example, in July 2024, we submitted a request to the FDA to expand the existing EUA for PEMGARDA to cover treatment of mild-to-moderate COVID-19 in certain immunocompromised patients, and thereafter we provided the FDA with updates as the SARS-CoV-2 virus evolved and we generated data for new variants as part of our ongoing industrial virology effort. The EUA process in the U.S. does not rely on a statutory timeline such as the timelines embedded into PDUFA-based regulatory actions such as a BLA approval

process, and the FDA has discretion with respect to EUAs in making its determination about whether, based on the totality of scientific evidence available, the known and potential benefits of a product candidate outweigh the known and potential risks. In February 2025, the FDA declined our EUA amendment request.

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 develop and periodically introduce new mAbs that can broadly neutralize SARS-CoV-2. Beyond PEMGARDA, which is currently authorized only for pre-exposure prophylaxis of COVID-19 in certain immunocompromised patients, we may fail to deliver future mAbs that effectively prevent or treat symptomatic COVID-19. Even if we are able to identify and develop such mAbs, such as VYD2311, we cannot ensure that such product candidates will achieve regulatory authorization or approval, 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 continuously discover and engineer new mAb candidates that can be leveraged to exert continuous pharmaceutical activity in the face of viral evolution. 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 regulatory 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 product profile, including the route of administration, and 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.

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 only for pre-exposure prophylaxis of COVID-19 in certain immunocompromised patients. VYD2311 is in Phase 3 clinical development. 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 authorization or approval in that other jurisdiction. To the extent that the results of our 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 or authorization 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 authorization or approval would delay or prevent commercialization of that product candidate and adversely impact our business and prospects.

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);
- 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 or desire to modify a trial protocol;
- unforeseen safety issues;
- emergence of dosing issues;
- lack of effectiveness data during clinical trials, including as a result of lower than anticipated viral attack rates in a study population that may inhibit the clinical trial from producing meaningful, statistically valid results, or require expanding the size of the clinical trial, which may be time-consuming and costly;
- 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 guidance or requirements for authorizing or approving our product candidates, or such guidance or 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.

PEMGARDA has not been approved, but has been authorized for emergency use by the FDA under an EUA. 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 or to other regulatory authorities 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, including those that are part of our REVOLUTION clinical program for VYD2311. 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 Section 564 of the FDCA permitting the FDA to authorize COVID-19 drugs and biologics for emergency use, such as the EUA for PEMGARDA, will continue to be in place for an extended period of time. If the EUA for PEMGARDA is terminated or revoked, we will be unable to sell PEMGARDA and instead would need to pursue traditional regulatory approval processes, which are

lengthy, time consuming and inherently unpredictable, and which we may determine not to pursue. If we are not able to maintain regulatory authorization for PEMGARDA, our business will be substantially harmed.

PEMGARDA is our first and only product candidate that has received regulatory authorization. PEMGARDA is not approved, but has been authorized for emergency use by the FDA under an EUA only for pre-exposure prophylaxis of COVID-19 in certain immunocompromised patients. Such EUA authorizes us to market and sell PEMGARDA in the U.S. under certain conditions. The FDA may issue an EUA during a public health emergency declared under the FDCA if the FDA determines that the known and potential benefits of a product outweigh the known and potential risks and if other regulatory criteria are met. 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 COVID-19 drugs and biologics, subject to the terms of any authorization issued by the FDA. The EUA 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 the FDA may no longer issue EUAs for products covered by that declaration. Accordingly, there is no guarantee of the duration for which we will be able to maintain the PEMGARDA EUA. 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 under Section 564 of the FDCA, unless the declaration is terminated or authorization is revoked sooner.

We may not 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 in the European Union until we receive marketing authorization from the European Commission, or other required regulatory authorization or approval in other countries. Other than the EUA for PEMGARDA in the U.S. for pre-exposure prophylaxis of COVID-19 in certain immunocompromised patients, we have not obtained regulatory authorization or approval for any other product candidate, and it is possible that we may never be successful in expanding the authorized use of PEMGARDA or obtain regulatory authorization or approval for any other product candidates in the future, particularly in light of the FDA's discretion with respect to EUAs in the U.S. in making its determination about whether, based on the totality of scientific evidence available, the known and potential benefits of a product candidate outweigh the known and potential risks.

Although we received an EUA from the FDA for PEMGARDA, there is no guarantee that we will apply for an EUA or similar authorization for any other product candidates or, if we do apply, that we will be able to obtain an EUA or such similar authorization. If an EUA or other authorization is granted, we will rely on the FDA or other applicable regulatory authority policies and guidance governing products authorized in this manner in connection with the marketing and sale of our product. If these policies and guidance change unexpectedly and/or materially or if we misinterpret them, potential sales of our product could be adversely impacted. 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.

If an existing EUA, such as the EUA for PEMGARDA, is revised or revoked, we would be unable to sell our product candidate and instead, we would need to pursue traditional regulatory approval processes. 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.

The FDA and other regulatory authorities may also 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. Further, evolving or changing plans or priorities at the FDA or other regulatory bodies, including based on regulatory policy changes, such as those at U.S. agencies such as HHS, FDA and the U.S. Centers for Disease Control due to the change in U.S. presidential administration in January 2025, may significantly impact our ability to obtain or maintain an EUA, including our EUA for PEMGARDA.

We may not succeed in obtaining the regulatory approval necessary to sell our product candidates.

We have devoted significant financial resources and business efforts to the development of our product candidates. While PEMGARDA is our first and only product candidate that has received regulatory authorization, we cannot be certain that PEMGARDA, VYD2311 or any of our other product candidates will receive full regulatory approval.

The development of a product candidate and issues relating to its approval and marketing are subject to extensive regulation by the FDA and other regulatory authorities in the U.S. and by comparable regulatory authorities in other countries. Other than pursuant to an EUA, such as the EUA for PEMGARDA, we are not permitted to market our product candidates in the U.S. until we receive approval of a BLA from the FDA. The time required to obtain regulatory approval by the FDA or comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends on numerous factors, including the substantial discretion of the regulatory authorities. In addition, conditions for approval, regulations, standards of care or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. In August 2025, we announced that we received and aligned with advice from the FDA on a compact and, therefore, rapid pathway to potential BLA for mAb candidate VYD2311 for the prevention of COVID-19. In October 2025, we announced the FDA subsequently cleared our IND application and provided feedback to advance our REVOLUTION clinical program for VYD2311 and, in December 2025, we announced initiation of our DECLARATION pivotal clinical trial. However, we cannot be certain that VYD2311 will receive the BLA that we are pursuing in the U.S.

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. BLA submissions must also include significant information regarding CMC for the product candidate. 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.

Even if a product candidate is approved, the FDA may limit the indication for which the product candidate may be marketed, require extensive warnings on the product labeling, or impose other expensive and time-consuming requirements or restrictions as conditions of approval, such as post-market requirements and commitments to conduct clinical trials or nonclinical testing, additional safety monitoring and reporting obligations, or restrictions on sale and distribution. Regulators in other countries and jurisdictions have their own procedures for approval of product candidates with which we must comply prior to marketing in those countries or jurisdictions.

Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the U.S. or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, preclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding our product

candidates or other products. Also, following approval, regulators may impose new or additional requirements or restrictions, or may withdraw regulatory approval altogether.

Any delay or setback in the regulatory approval or commercialization of any of our product candidates could delay our ability to generate revenue and negatively impact our business, financial condition, results of operations and prospects.

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.

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 PEMGARDA is 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 or other infectious diseases may adversely impact the development or commercial success of our product candidates.

The clinical and commercial success of our mAb therapies will depend in part on public acceptance of the use of mAb therapies to prevent or treat COVID-19 or other infectious diseases. 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. Additionally, our success may be impacted by overall evolving dynamics in the commercial market for COVID-19 therapeutics, such as greater seasonality of demand, particularly as COVID-19 has developed into an endemic disease.

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 authorization or approval of our product candidates, stricter labeling requirements for those product candidates that are authorized or approved or 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 authorizations or 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 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 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;
- 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.

The accelerated approval pathway, a Fast Track designation or a 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 full marketing approval.

The FDA has established various expedited drug development programs to facilitate more rapid and efficient development, review and approval of certain types of drugs. Such programs include accelerated approval, Fast Track designation and breakthrough therapy designation. In December 2025, the FDA granted VYD2311 Fast Track designation for the prevention of COVID in individuals with underlying risk factors for severe COVID. The FDA has broad discretion on whether or not to admit a drug candidate for these programs, so even if we believe a particular product candidate is eligible for an expedited drug development program, we cannot be sure that the FDA would agree. Even if any of our product candidates is admitted to any of the expedited drug development programs, such as the Fast Track designation granted for VYD2311,we may not experience a faster development process, review or approval compared to conventional FDA timelines, and the FDA may still ultimately decide to not grant full marketing approval to VYD2311 or any of such other product candidates.

For example, we may pursue accelerated approval or the equivalent thereof in foreign jurisdictions (where available), for our product candidates. The FDA may grant accelerated approval to a product candidate for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product candidate has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, and 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 a grant of accelerated approval, the FDA may require that the sponsor perform one or more controlled post-marketing clinical trials. Accelerated approval of a product candidate may be withdrawn if these trials fails to verify clinical benefit or do not demonstrate sufficient clinical benefit to justify the risks associated with the product candidate (e.g., shows a significantly smaller magnitude or duration of benefit than was anticipated based on the observed effect on the surrogate).

The FDA granted Fast Track designation for VYD2311 in December 2025, and we may pursue Fast Track designation for other product candidates in the U.S., or the equivalent thereof in foreign jurisdictions (where available), which is designed to facilitate the development and expedite the review of therapies for serious conditions that fill an unmet medical need. A product candidate with a Fast Track designation may benefit from early and frequent communications with the FDA, be eligible for priority review and has the ability to submit a rolling application for regulatory review. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply or due to other issues, we will not receive the benefits associated with the Fast Track program. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

In addition, we may apply for breakthrough therapy designation in the U.S. 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. 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.

Granting accelerated approval, Fast Track designation or breakthrough therapy designation 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 accelerated approval, Fast Track designation or breakthrough therapy designation, the FDA may disagree and instead determine not to grant such designation. Even if one or more of our product candidates receives conditional approval via the accelerated approval pathway, the FDA may later decide that the product candidate no longer meets the qualifying criteria for such approval, or it may decide that the confirmatory trial(s) failed to verify the clinical benefit or demonstrate sufficient clinical benefit to justify the risks associated with the product candidate, and the FDA may withdraw its conditional approval and/or refuse to grant full approval. Furthermore, the receipt of a Fast Track designation or breakthrough therapy designation for a product candidate may not result in a faster development process, review or full approval compared to product candidates considered for approval under conventional FDA procedures or the traditional FDA approval pathway, and such designations would not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify for Fast Track designation or breakthrough therapy designation, the FDA may later decide that the product candidate no longer meets the conditions for qualification, or it may otherwise not shorten the application review period.

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, and the manufacturing and development of VYD2311, our next generation mAb candidate for COVID-19. 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, VYD2311 or any new 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 of antibody therapies for COVID-19 and other serious viral infectious diseases, such as RSV and measles, 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 authorized or 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 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 evolution and impact 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.

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 future public health outbreak, pandemic or epidemic.

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, 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.

Our product candidates 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 are 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.

Risks Related to the Manufacturing of our Product Candidates

Monoclonal antibody therapies are complex, difficult and time-consuming to manufacture, and we currently rely on a single contract manufacturer for our COVID-19 product candidates. We could experience manufacturing problems, may be unable to access desired future 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.

The manufacture of mAbs 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 rely on WuXi Biologics, a CDMO, for the development and manufacture of our COVID-19 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.

Given the complex, difficult and time-consuming nature of manufacturing our product candidates, we must devote significant resources to the manufacture of our product candidates for clinical and potential commercial supply prior to receiving regulatory authorization or approval, and we may not realize a return on our investment in such supply if a product candidate is not ultimately authorized or approved. For example, we built supply of adintrevimab in anticipation of seeking regulatory authorization, but 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. More recently, we have incurred substantial costs in building supply of VYD2311, which is currently in Phase 3 development, and we cannot be certain as to if or when we will receive regulatory approval for such product candidate. Even if we ultimately receive regulatory authorization or approval to commercialize a product candidate, such as the EUA for PEMGARDA, if sales do not meet the expected forecasts or a portion of our inventory becomes expired, it may be necessary to write down or write off such obsolete inventory, which could adversely affect our operating results.

While we believe that we have secured sufficient supply to meet demand for PEMGARDA and anticipated initial demand for VYD2311, if approved, any delay, failure or inability to manufacture or test on a timely basis in the future could impact the timelines for our future 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 COVID-19 product candidates for clinical trials and commercial supply, 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, acceptable pricing terms, and on a timely basis, could harm our business.

Manufacturing and testing our product candidates and commercialization of any authorized or approved products requires many specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture and testing of our product candidates. For example, we are reliant on WuXi Biologics, our current CDMO, as the procurer of the raw materials used in the manufacture of our COVID-19 product candidates, 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 for our COVID-19 product candidates. We have partnered with WuXi Biologics for CMC development and for clinical and commercial drug substance and drug product supply. While we believe that we have secured sufficient supply to meet demand for PEMGARDA and anticipated initial demand for VYD2311, if approved, the loss of this CDMO, a disruption in production at this CDMO or the inability of this CDMO to timely manufacture sufficient quantities on acceptable pricing terms 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. 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 platform approach to facilitate the generation of mAbs to exert continuous pharmaceutical activity in the face of viral evolution, 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 (and similar notifications and approvals by other comparable foreign regulatory authorities). 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 may be 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 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.

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 ("HCPs") 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. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%. 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, 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. For example, in July 2024, we submitted a request to the FDA to expand the existing EUA for PEMGARDA to cover treatment of mild-to-moderate COVID-19 in certain immunocompromised patients, which request was denied by the FDA in February 2025.

Our product candidates 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, including compared to any 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 maintain and expand our 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 SARS-CoV-2 variants.

The commercial success of our product candidates, if authorized or approved, is dependent upon market acceptance by physicians, HCPs and patients, which will be informed, in part, by cost, convenience, route of administration, safety and efficacy, including efficacy against emerging SARS-CoV-2 variants over time.

If we are unable to continue 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 began commercializing PEMGARDA after we received an EUA from the FDA in March 2024. As a result, we have 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, or any other

product candidate that receives regulatory authorization or approval, for appropriate patients in a manner that complies with applicable laws and regulations.

We will need to continue to build and maintain a commercial infrastructure to support the marketing and distribution of PEMGARDA and any other product candidates that may be authorized or approved in the future. To support the commercialization of PEMGARDA, we initially directly hired key leaders for our sales, marketing, market access, and medical affairs teams, and leveraged contract organizations for certain field-based roles. We subsequently determined to invest in direct hire resources, including an internal sales force.

There are risks involved with both establishing our own commercialization capabilities and with entering into arrangements with contract organizations. To the extent that we rely on third parties to perform sales, marketing or distribution services, 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. On the other hand, there are risks involved with establishing our commercial infrastructure. For example, establishing and training our own commercial team is expensive and time consuming.

Factors that may inhibit our efforts to continue to build and maintain our commercialization capabilities include:

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

If we 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.

A key element of our business strategy is the continued expansion of our marketing infrastructure and building brand awareness. As we continue to 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 Invivyd-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.

Our commercial prospects may be harmed if academic or other third-party labs not related to us generate virologic activity data that creates doubt regarding the neutralization activity of pemivibart or any other of our product candidates, even if such data is ultimately shown to be inconsistent with neutralization data generated through our industrial-grade virology efforts.

From time to time, academic or other third-party labs not related to us may produce and run tests on their own molecules meant to resemble our molecules, such as pemivibart, or may run tests on our molecules utilizing differing assays and put neutralization findings of unknown quality into the public domain. In connection with the EUA for PEMGARDA, the FDA has acknowledged that neutralization findings from sources other than our independent, contracted vendor may differ due to, among other reasons, assay differences or because the molecule tested by other labs differs from pemivibart in sequence. Nevertheless, publicly available neutralization data against emerging SARS-CoV-2 variants are reviewed by the FDA and may be factored into the totality of evidence when considering the potential for adequate neutralization activity of PEMGARDA to support continued emergency use authorization.

To the extent that virologic activity data in the public domain generated by academic or other third-party labs not related to us creates doubt regarding the neutralization activity of pemivibart or our other product candidates, it could adversely impact our regulatory authorization and market acceptance by HCPs or patients, particularly if such publicly available neutralization findings are referenced by the FDA in relation to the regulatory authorization of any product candidate of ours, which would adversely affect our commercial prospects and ability to generate revenues, even if such data is preliminary, non-peer-reviewed, and/or generated with molecules that are not authentic Invivyd molecules, and even if such data is ultimately shown to be inconsistent with neutralization data generated through our industrial-grade virology efforts.

For example, in October 2024, we withdrew formal revenue guidance for FY2024 following growth headwinds after the FDA updated the PEMGARDA Fact Sheet for HCPs in August 2024 to include a link to contested, non-peer-reviewed neutralization data of a non-pemivibart antibody generated by an academic lab, which indicated that PEMGARDA may have reduced susceptibility to certain SARS-CoV-2 variants, including KP.3.1.1. In September 2024, we announced that pseudovirus *in vitro* neutralization data generated by our independent, contracted vendor as part of our industrial-grade virology efforts showed continued neutralizing activity of PEMGARDA against KP.3.1.1 and other SARS-CoV-2 variants tested, and later that month, the FDA re-issued an updated PEMGARDA Fact Sheet for HCPs to provide accurate *in vitro* neutralization activity of PEMGARDA against dominant circulating variants, including KP.3.1.1. However, this series of events resulted in confusion in the HCP and vulnerable population communities with respect to PEMGARDA and negatively impacted our net product revenue growth.

If academic or other third-party labs not related to us generate virologic activity data that creates doubt regarding the neutralization activity of pemivibart or any other of our product candidates, our regulatory authorization and our commercial prospects may be harmed, even if such data is ultimately shown to be inconsistent with neutralization data generated through our industrial-grade virology efforts.

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 authorized or approved indications. We train our marketing and sales force against promoting our products for uses outside of the authorized or approved indications, 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 medicinal products in the European Union is subject to European Union and Member States' national laws, which provide comprehensive regulatory requirements, including restrictions on promotional content, comparative advertising and unfair commercial practices, and 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, including PEMGARDA, may face significant competition from vaccines, antiviral agents and other therapeutics for COVID-19 that are currently available or in development.

Other biotechnology and pharmaceutical companies are developing therapeutics for COVID-19 or vaccines against SARS-CoV-2, the virus that causes COVID-19, including large pharmaceutical companies that 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 our product candidates 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. Our success is also subject to the risk of current and future disruptive technologies, such as AI; if our competitors are able to more effectively utilize any such new technologies,

including but not limited to those that may involve AI or be created using AI, to discover, develop and commercialize products that compete with any of our product candidates, such technologies could adversely impact our ability to compete against 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 PEMGARDA and our product candidates depends 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 and may change from one calendar year to the next. 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 2023 Physician Fee Schedule Final Rule, and reaffirmed in subsequent Calendar Year

Rulemaking, a policy 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 coverage information for any such product once it has been granted an EUA. A significant delay in publication of product specific billing codes and their associated payment rates could impact initial prescription rates by providers and demand by patients. Furthermore, a delay by CMS in publishing updated payment limits following any price increase of a product could impact prescription rates by providers or lead to deferment in treatment for patients, which could adversely affect our sales.

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 authorized or 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 authorized or 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 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 European Union's HTA Regulation, which started to apply on January 12, 2025, aims to harmonize the clinical benefit assessment of HTA across the European Union. 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 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 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. 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 authorization 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 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 reactions included systemic infusion-related reactions and hypersensitivity reactions, local infusion site reactions, and infusion site infiltration or extravasation. Anaphylaxis has been observed with PEMGARDA, and the PEMGARDA Fact Sheet for HCPs 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 continue 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. The multitude and complexity of our information systems may make them susceptible to service interruption, cybersecurity incidents, 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 cybersecurity incidents 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, social engineering (e.g., phishing attacks), attacks enhanced or facilitated by AI, and other similar threats. Further, adoption of AI tools by us or by third parties may pose new cybersecurity challenges. Threat actors may use AI tools to automate and enhance cybersecurity attacks against us. We use software and platforms designed to detect such cybersecurity threats, including AI-based tools, but these threats could become more sophisticated and harder to detect and counteract, which may pose significant risks to our data security and systems. 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 data, 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 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, significantly increase our costs to recover or reproduce the data, and reduce trial participants' or patients' trust in us. 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 ("IT"), 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 cybersecurity incidents 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 IT 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 actual or perceived information security failures or cybersecurity incidents attributed to our third-party service providers as they relate to the information we share with them. While we may be entitled to damages if our third-party service providers fail to satisfy their cybersecurity-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

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. Moreover, data protection laws and regulations in the jurisdictions where we operate often require "reasonable," "appropriate" or "adequate" technical and organizational cybersecurity measures, and the interpretation and application of those laws and regulations are often uncertain and evolving; there can be no assurance that our cybersecurity measures will be deemed adequate, appropriate or reasonable by a regulator or court. Further, even security measures that are deemed appropriate, reasonable, and/or in accordance with applicable legal standards or requirements may not be able to protect the information we maintain. 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. It could also interfere with our ability to comply with financial or other legal reporting requirements or result in loss of competitive position and, furthermore, the 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 investigations or 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 could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws and federal and state consumer protection laws and regulations, including Section 5 of the FTC Act and the FTC Health Breach Notification Rule, 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, as amended by the Health Information Technology for Economic and Clinical Health Act, and the regulations promulgated thereunder ("HIPAA"). HIPAA imposes privacy and security obligations on "covered entities," 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 criminal 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, and subject to other civil and/or criminal penalties if we obtain, use, or disclose information in a manner not permitted by other privacy and data security and consumer protection laws.

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, and has taken the position that 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 a company handles consumers' personal information; such failure may also constitute unfair or deceptive acts or practices in violation of the FTC Act. The FTC also has the power to enforce the Health Breach Notification Rule, which imposes notification obligations on companies for breaches of certain health information contained in personal health records. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

States are also continuing to adopt new laws or amend existing laws, requiring attention to frequently changing regulatory requirements. For example, the CCPA gives California consumers (as defined by law) certain 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. It also requires covered companies to provide disclosures to California consumers and includes opt-out rights for certain uses of sensitive data. Under the CCPA, the California Privacy Protection Agency is authorized to issue and has issued substantive regulations, including with respect to risk assessments and cybersecurity audits, which could result in increased privacy and information security enforcement. The 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. Similar state consumer protection laws have passed in other states and there are now more than a dozen in effect. Future laws may have potentially conflicting requirements that would make compliance challenging and present legal risk and could result in significant compliance costs. Health-specific consumer privacy laws also exist in multiple states, including Washington and Nevada.

In Europe and the United Kingdom, the GDPR, including as implemented in the United Kingdom, governs the processing of personal data of individuals within the European Economic Area ("EEA") and the United Kingdom, including clinical trial data. Among other things, the GDPR imposes requirements regarding the security of personal data, notification of data breaches to the competent national authorities, and requires having lawful basis for processing personal data (which may in certain situations require explicit consent of data subjects). The GDPR imposes substantial fines for breaches and violations (for the most serious violations 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 generally restricts the transfers of personal data from the EEA, including the European Union and the United Kingdom, to other jurisdictions that the European Commission/United Kingdom Secretary of State, as applicable, does not recognize as having "adequate" data protection laws unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. With respect to the U.S., on July 10, 2023, the European Commission adopted its adequacy decision for the EU-US Data Privacy Framework, enabling personal data to be transferred from the European Union to U.S. organizations that are certified under the Data Privacy Framework.

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/revised, 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.

Moreover, as a result of the broad scale release and availability of AI technologies such as generative AI, there is a global trend towards more regulation (e.g., the EU AI Act and AI laws passed in U.S. states) to ensure the ethical use, privacy, and security of AI and the data that it processes. Compliance with such laws will likely be an increasing and substantial cost in the future.

With the GDPR, CCPA and other laws, regulations and other obligations relating to privacy and data protection imposing evolving 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 or contractual obligations, 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. Accordingly compliance efforts will likely be an increasing and substantial cost in the future. Federal and foreign regulators, state attorneys general, and plaintiffs' attorneys, including class action attorneys, have been and will likely continue to be active in this space.

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 nonclinical activities 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 or maintain regulatory authorization or approval or successfully commercialize product candidates, or such authorization or approval or commercialization may be delayed or impaired, and our business may be substantially harmed.

We have engaged CROs and other third parties to conduct nonclinical activities and clinical trials for our product candidates, and to monitor and manage data. We expect to continue to rely on third parties such as clinical data management organizations, medical institutions and clinical investigators to conduct such activities and trials. We also rely on third parties for their research and discovery capabilities, including the nonclinical activity of assay development and virology testing of our product candidates. 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 on commercially reasonable terms, if at all. Switching or adding CROs or other third-party vendors requires management time and focus, and may involve substantial cost or result in delays that materially impact our ability to meet our desired program timelines for our product candidates.

Though we intend to carefully manage our relationships with our CROs and other third-party vendors, there can be no assurance that we will not encounter challenges or delays in the future or that any such delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

In addition, any third parties conducting our nonclinical activities or 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 programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality or accuracy of the nonclinical, clinical or other data they generate or otherwise obtain is compromised or not timely made available to us or regulatory authorities, due to the failure to adhere to applicable protocols, regulatory requirements, contractual obligations or for other reasons, our preclinical studies or clinical trials may be extended, delayed or terminated, the strength and reliability of our data may be adversely impacted, which may impact our ability to obtain or maintain regulatory authorization or approval, or result in modification to the regulatory authorization or approval documents (e.g., EUA fact sheet, letter of authorization or prescribing information), and may impact our ability to successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates may be harmed, our costs could increase substantially and our ability to generate revenue could be impaired significantly. For example, following receipt of EUA from the FDA in March 2024 for PEMGARDA (pemivibart) for the pre-exposure prophylaxis (prevention) of COVID-19 in certain adults and adolescent individuals (12 years of age and older weighing at least 40 kg), we were informed in mid-July 2024 by our third-party authentic virus neutralization assay ("AVNA") vendor that a possible contamination event may have impacted the AVNA potency value generated by such vendor for pemivibart against JN.1, which was the dominant circulating SARS-CoV-2 variant in the U.S. between January 2024 and April 2024. Along with the pseudotyped viral neutralization assay ("PVNA") potency value for pemivibart against JN.1, the original PEMGARDA Fact Sheet for HCPs reflected the AVNA potency value for pemivibart against JN.1. As a result of the possible contamination event at our third-party AVNA vendor that may have impacted the AVNA potency value for pemivibart against JN.1, the FDA made modifications to the PEMGARDA Fact Sheet for HCPs, including, among other changes, removal of the AVNA potency value for pemivibart against JN.1 and incorporation of certain other available information for HCPs to consider when determining whether to prescribe PEMGARDA.

Our reliance on CROs and other third parties reduces our control over our nonclinical activities and clinical trials, but does not relieve us of our regulatory 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 cGCPs, 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 or comparable foreign regulatory authorities may require us to perform additional clinical trials before authorizing or approving our product candidates. 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 authorization or approval process for our product candidates.

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, which may lead to the delay or denial of regulatory authorization or 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 such third parties 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.

If our CROs or other third-party vendors do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain or maintain regulatory authorization or

approval or successfully commercialize product candidates, or such authorization or approval or commercialization may be delayed or impaired, and our business may be substantially harmed.

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

We currently rely on third parties for manufacturing, testing, labeling, packaging, storing and distributing our product candidates. We do not own or operate any facilities for product manufacturing, testing, labeling, packaging, or storage.

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 rely on WuXi Biologics as our CDMO to manufacture our COVID-19 product candidates for clinical and commercial supply. 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 currently rely exclusively on WuXi Biologics' China-based facilities for clinical supply and commercial supply of our COVID-19 mAbs. 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. There is additional uncertainty as it is not known what actions, including the imposition of potential sanctions or tariffs, may be taken by the U.S. presidential administration. 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 December 2025, the BIOSECURE Act was enacted into law as part of the National Defense Authorization Act for fiscal year 2026. The new law prohibits U.S. federal executive agencies from contracting with any entity where the biotechnology equipment or services of a "biotechnology company of concern" would be used in the performance of that contract. Biotechnology companies of concern will include entities (1) listed on the Department of Defense Section 1260H list of "Chinese military companies" that are determined through an interagency process led by the Office of Management and Budget to be involved in the manufacturing, distribution, provision or procurement of any biotechnology equipment or service; and (2) additional entities later designated as biotechnology companies of concern through the same interagency process led by the Office of Management and Budget. The BIOSECURE Act has the potential to severely restrict our ability to purchase services or products from, or otherwise collaborate with, such "biotechnology companies of concern" without losing the ability to contract with, or otherwise receive funding from, the U.S. government. We do business with foreign companies, and it is possible some of our services providers could be impacted by the new legislation. WuXi Biologics is not currently identified as a "biotechnology company of concern," but there is no assurance that this will remain the case. 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 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.

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.

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.

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, including PEMGARDA, 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, 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. Similarly, a derivation proceeding may be utilized to determine if an inventor in an earlier-filed application derived their invention from information that we did not know was disclosed without authorization by someone who later filed an application.

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 IT 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 substantially 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 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 forgoing, and, in spite of our efforts, our current and future licensors might conclude that we have materially breached our obligations under our license agreements and might therefore terminate such license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements.

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

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

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

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

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

future. An inability to obtain, enforce, and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

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

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 (*e.g.* patent applications do not publish until 18 months from the filing of a provisional patent application). 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. For example, there were discussions at the World Trade Organization (the "WTO") regarding the role of intellectual property in the context of the COVID-19 response, including 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, it is possible that certain countries may take steps to facilitate compulsory licenses that permit the distribution of a 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.

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 also utilize marks that have not been registered with the USPTO and rely on common law rights to those marks, which may be challenged. 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. For example, in October 2023, Ipsen Biopharm, LTD ("Ipsen") 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". We resolved this issue by entering into a coexistence agreement with Ipsen in which Ipsen withdrew their oppositions of the INVIVYD mark and we agreed to limit our use of INVIVYD to a "house mark."

If we are found to infringe the trademark rights of a 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 substantially 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 play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing authorization or 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 and patients. 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, 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 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 for payment of government funds. 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 a variety of alleged misconduct, including, for example, 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, 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," certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," certain persons or entities that create, receive, maintain or transmit protected 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 protected health information. Other analogous state and foreign laws govern the privacy and security of health information in some circumstances. Additionally, numerous federal and state laws, including state security breach notification laws, and federal and state consumer protection and

privacy laws, (including, for example, Section 5 of the FTC Act and the FTC Health Breach Notification Rule, and the CCPA, as amended by the CPRA) govern the collection, use and disclosure of personal information. Many of these laws differ from each other in significant ways and thus complicate compliance efforts;

- HIPAA also created 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, including those by private payors. 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.

If and when 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.

If and when 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 other 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.

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, 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 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 2032. Under current legislation, sequestration is currently set at 2% through 2033. 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 government has shown substantial interest in taking a variety of measures aimed at lowering U.S. prescription drug prices to align with the lowest prices available for the same drugs in comparable developed nations (so called "most favored nation" pricing). As another example of federal activity in this area, 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 HHS to negotiate prescription drug prices with companies, subject to a specified cap, for Medicare units of a specified number of certain FDA approved or licensed 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 made 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 for an applicable drug 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 prohibited Medicare Part D plans from imposing cost-sharing for certain vaccines that are recommended by the Advisory Committee on Immunization Practices.

In addition, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law. The OBBBA is projected to decrease federal health care spending by approximately $1 trillion by reducing Medicaid spending and enrollment and making changes to federal Medicare spending. The law also made changes to ACA marketplace enrollment that are projected to decrease the number of individuals with marketplace coverage. It is unclear if these changes will impact demand for our products, once authorized or approved.

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. Additionally, some individual states have begun establishing Prescription Drug Affordability Boards to review high-cost drugs and, in some cases, set upper payment limits.

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 attract and 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. Executive officers may terminate employment with us at any time, and the ability to attract a key executive to replace that position and the ability to retain additional key executives are critical to our success. We do not maintain "key person" insurance for any of our executives or employees.

Since May 2024, William Duke, Jr., our Chief Financial Officer, has served as our "principal executive officer." Mr. Duke assumed such role following the separation from Invivyd of our previous Chief Executive Officer and Interim Chief Executive Officer and is expected to continue to serve until a permanent successor can be identified. Executive leadership transition periods can often be difficult and may result in changes in leadership strategy and style. There may be organizational changes or changes in business strategy in connection with any future Chief Executive Officer transition, and we can provide no assurances that any such changes will be beneficial or will have the desired impact on the company.

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.

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, 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

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 1, 2026, our common stock has traded at prices ranging from $0.35 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 timely identify, develop, obtain authorization or approval for, and commercialize mAbs that exert continuous pharmaceutical activity in the face of viral evolution;
- the timing, progress and results of our clinical trials, including our REVOLUTION clinical program for VYD2311, 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 issuance of a "refusal to file" letter or a request for additional information;
- our ability to maintain our existing EUA for PEMGARDA, and the scope and timing of any amendments thereto;
- delays in or termination of clinical trials, such as DECLARATION and LIBERTY;
- adverse regulatory decisions, including failure to receive any requested amendment to our existing EUA for PEMGARDA, or failure to receive regulatory authorization or approval of any other product candidate;
- serious safety concerns related to the use of PEMGARDA, VYD2311 or any other product candidate;
- the timing, progress and results of our efforts to develop potential best-in-class antibody therapies across multiple virus targets beyond SARS-CoV-2, including RSV and measles;
- 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;
- failure to comply with listing requirements of The Nasdaq Stock Market ("Nasdaq");
- 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, disruptions to global supply chain, tariff uncertainty or other macroeconomic factors, 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. 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 lawsuit was dismissed with prejudice in September 2024. However, we may be the target of similar litigation in the future.

There can be no assurance that we will continue to be able to comply with the continued listing standards of Nasdaq.

Our common stock is listed on the Nasdaq Global Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly held shares, market value of listed shares, minimum bid price per share, and minimum stockholders' equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements and are unable to timely regain compliance, we may be delisted from the Nasdaq Global Market.

For example, on December 27, 2024, we received a letter from Nasdaq notifying us that, because the closing bid price for our common stock had closed below $1.00 per share for 30 consecutive business days, we no longer complied with the minimum bid price requirement for continued listing on the Nasdaq Global Market pursuant to Nasdaq Listing Rule 5450(a)(1) (the "Minimum Bid Price Requirement"). We then received a letter from Nasdaq on February 21, 2025 notifying us that we had regained compliance with the Minimum Bid Price Requirement, and the matter with respect to that period of non-compliance was closed.

Subsequently, on April 21, 2025, we received a new letter from Nasdaq notifying us that, because the closing bid price for our common stock had again closed below $1.00 per share for 30 consecutive business days, we no longer complied with the Minimum Bid Price Requirement. We then received a letter from Nasdaq on September 22, 2025 notifying us that we had regained compliance with the Minimum Bid Price Requirement, and the matter with respect to that period of non-compliance was closed.

To the extent that we are unable to maintain compliance with Nasdaq's continued listing requirements, there is a risk that our common stock may be delisted from Nasdaq. Delisting from Nasdaq may adversely affect our ability to raise additional financing through the public or private sale of equity securities, significantly affect the ability of investors to trade our securities, or negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in potential business development opportunities.

Furthermore, if we are delisted from Nasdaq and we are not able to list our common stock on another exchange, our common stock may be eligible to trade on an over-the-counter system, such as the OTCQB market, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the-counter quotation system.

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 ("DGCL"), 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.

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 December 31, 2026. 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 December 31, 2026. 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.

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 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 U.S. 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

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

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, 2025, we had U.S. federal net operating loss ("NOL") carryforwards of $485.8 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, 2025, we had state NOL carryforwards of $286.9 million, which may be available to reduce future taxable income, of which $41.8 million have an indefinite carryforward period while the remaining $245.1 million begin to expire in 2031. As of December 31, 2025, we also had U.S. federal and state research and development tax credit carryforwards of $24.8 million and $7.7 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2040 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 the U.S. presidential administration, 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 or review other regulatory submissions can be affected by a variety of factors, including government budget and funding levels, a reduction in the FDA's workforce and its ability to hire and retain key personnel and accept the payment of user fees, shifting policy priorities as a result of the current U.S. presidential administration and political appointees tasked to oversee the agency, 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 increase the time to meet with and receive agency feedback, review and/or approve our submissions, conduct inspections, issue regulatory guidance, or take other actions that facilitate the development, approval and marketing of regulated products, which would adversely affect our business. In addition, government proposals to reduce or eliminate budgetary deficits may include reduced allocations to the FDA and other related government agencies. It is unclear how certain executive actions or other potential actions by the U.S. presidential administration or other parts of the federal government will impact the FDA or other regulatory authorities that oversee our business. These budgetary pressures may reduce the FDA's ability to perform its responsibilities. If a significant reduction in the FDA's workforce occurs, the FDA's budget is significantly reduced or 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 or take other actions critical to the development or marketing of our product candidates, which could have a material adverse effect on our business.

Unfavorable global economic conditions and geopolitical events, including as a result of trade tensions between the U.S. and China, could adversely affect our business, financial condition or results of operations, including conduct of our clinical trials and our manufacturing activities.

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, terrorism or other political 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, higher inflation and interest rates, political disruption or other geopolitical events, including an expansion of current global military conflicts 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. Additionally, political pressures, shifting public health priorities, and evolving FDA policies under the new U.S. presidential administration could also impact the demand for COVID-19-related prevention and treatment measures, affecting the commercial potential of our COVID-19 product candidates.

A weak or declining economy or political disruption, including any international trade disputes, or changes in laws or policies governing the terms of international trade, and in particular increased trade restrictions, tariffs or taxes on imports from countries where we manufacture products, such as China, could strain our manufacturer or suppliers, possibly resulting in supply disruption or increased manufacturing and distribution costs. For example, in 2025, the U.S. imposed or threatened tariffs on certain imports from countries around the world, including Canada, Mexico and China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies and tariff uncertainty could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets.

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 IT function and are designed to align with key principles of 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 ten 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. We also use a number of means to assess cyber risks related to our third-party service providers, including conducting due diligence in connection with onboarding new vendors and periodic ongoing due diligence with key third-party vendors. We also seek to collect and assess cybersecurity audit reports and other supporting documentation when available and include appropriate security terms in our contracts where applicable as part of our oversight of third party providers.

As of December 31, 2025, 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. For discussion of cybersecurity risks, please see Item 1A, "Risk Factors."

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 our 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 Financial Officer to discuss our cybersecurity threat landscape, address opportunities for improvement and issues, and evaluate solutions to cover identified gaps. Our Head of IT, in collaboration with members of senior management, reports significant cybersecurity matters to our Audit Committee, consistent with the Incident Response Policy.

Item 2. Properties.

We operate as a hybrid company with employees working at our principal office in New Haven, Connecticut, our laboratory in Newton, Massachusetts and remotely.

Our principal office is located at 209 Church Street, New Haven, Connecticut 06510, where we lease office space for general and administrative purposes. We lease this space under a lease agreement that is scheduled to expire in May 2026.

In January 2026, we entered into an agreement to lease office space in New Haven, Connecticut for general and administrative purposes. The term of the lease will commence after the later of (i) the date on which landlord improvements to the premises are deemed to be substantially completed, or (ii) the delivery of the lender consent package. The lease has an initial term of one hundred twenty-nine months, measured from the lease commencement date.

Additionally, we lease laboratory and office space in Newton, Massachusetts for research and development purposes. We lease this space under a lease agreement that is scheduled to expire in December 2027. We believe that our facilities are sufficient to meet our current needs, and that, if we require additional physical facilities, we will be able to obtain additional facilities on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. We accrue liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and estimated exposure amount. Legal fees and other costs associated with such proceedings are expensed as incurred. As of December 31, 2025, we were not a party to any material legal proceedings.

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 1, 2026, there were 7 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

We did not issue any unregistered equity securities during the twelve months ended December 31, 2025.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the quarter ended December 31, 2025.

Item 6. [Reserved]

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

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

Overview

Invivyd, Inc. is a biopharmaceutical company focused on the discovery, development and commercialization of monoclonal antibody ("mAb") therapies for the prevention and treatment of serious viral infectious diseases. We are devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2, the virus that causes COVID-19. PEMGARDA® (pemivibart) is our first mAb to receive regulatory authorization and was designed to exert continuous pharmaceutical activity in the face of viral evolution.

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. COVID-19 persists and continues to impact patients, notably those who are immunocompromised, and combating this disease will require for years to come a variety of prevention and treatment options with demonstrated efficacy and safety. By leveraging our capabilities, which we have developed through our experience with adintrevimab and pemivibart and over five years in the COVID-19 space, we aim to develop mAbs that could be used in prevention or treatment of serious viral infectious diseases, starting with COVID-19 and expanding into other high-need indications, such as respiratory syncytial virus ("RSV") and measles.

On March 22, 2024, we received emergency use authorization ("EUA") from the U.S. Food and Drug Administration ("FDA") for PEMGARDA injection, for intravenous ("IV") 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.

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 Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

In January 2024, we nominated VYD2311, a next generation mAb candidate for COVID-19, as a drug candidate. VYD2311 is a mAb with high *in vitro* neutralization potency shown against prominent SARS-CoV-2 variants tested to date. In September 2024, we announced dosing of the first participants in a Phase 1/2 clinical trial of VYD2311. The Phase 1/2 randomized, blinded, placebo-controlled clinical trial evaluated escalating dosing as well as safety, tolerability, pharmacokinetics and immunogenicity of VYD2311 in healthy trial participants. The Phase 1/2 clinical trial was conducted in Australia and evaluated multiple dose levels of VYD2311 through various routes of administration, including exploration of intramuscular ("IM") administration and subcutaneous administration, which are designed to be more healthcare system- and patient-friendly than IV administration. In June 2025, we announced positive full Phase 1/2 clinical data for VYD2311 for both safety and pharmacokinetics. Like pemivibart, VYD2311 was engineered from adintrevimab, our investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 2/3 clinical trials for both the prevention and treatment of COVID-19.

In August 2025, we announced alignment with advice from the FDA on a compact and, therefore, rapid pathway to potential Biologics License Application ("BLA") approval for VYD2311 for the prevention of COVID-19. As part of Type C meeting feedback, the FDA advised that a single, randomized, placebo-controlled trial evaluating mAb efficacy in prevention of RT-PCR-confirmed symptomatic COVID-19 disease events could support a BLA submission for VYD2311 for the prevention of COVID-19 in a broad population of Americans (12 years of age and older, weighing at least 40kg), including immunocompromised people, subject to agreement on safety database size and pending full protocol review. In October 2025, we announced that the FDA cleared our Investigational New Drug ("IND") application for VYD2311 and provided feedback to advance our REVOLUTION clinical program, which is our development program for VYD2311. The

REVOLUTION clinical program includes two clinical trials, DECLARATION and LIBERTY. In December 2025, we initiated DECLARATION, which is a Phase 3 randomized, triple-blind, placebo-controlled clinical trial to evaluate VYD2311 safety and efficacy in prevention of symptomatic, RT-PCR-confirmed COVID-19 at three months, with either a single dose or monthly doses of VYD2311, each administered via IM injection, compared to placebo. DECLARATION is designed to support potential BLA submission, with top-line data anticipated in mid-2026. In February 2026, we announced alignment with the FDA on LIBERTY, which is designed as a Phase 3, randomized, double-blind clinical trial to evaluate the safety, serum virus neutralizing antibody responses, and pharmacokinetics of (1) VYD2311, (2) an mRNA COVID vaccine, and (3) co-administered VYD2311 with an mRNA COVID vaccine. The FDA has granted "Fast Track" designation for VYD2311 for the prevention of COVID-19 in individuals with underlying risk factors for progression to severe disease. Fast Track designation is a process designed to facilitate the development and expedite the regulatory review of drugs to treat serious conditions and fill an unmet medical need, including eligibility for priority review and rolling review of BLA submissions, if specified criteria are met.

In July 2025, we announced that we had formed the SPEAR (Spike Protein Elimination and Recovery) Study Group with leading investigators to structure and guide anticipated clinical trials evaluating the effects of broadly neutralizing anti-SARS-CoV-2 spike protein mAb therapy in people suffering from Long COVID or Post-Vaccination Syndrome ("PVS"). The SPEAR Study Group intends to launch multi-center translational clinical research on Long COVID and PVS using next-generation antibodies like our investigational mAb candidate VYD2311.

We engage in active SARS-CoV-2 variant monitoring of antiviral activity as part of our ongoing industrial virology effort, which leverages a consistent, high-quality, independent, third-party pseudoviral system that routinely tests authentic Invivyd-produced molecules and is supported by structure-based analytics. In September 2024, we announced continued neutralizing activity of PEMGARDA against SARS-CoV-2 variants KP.3.1.1 and LB.1 and attractive neutralization potency of VYD2311, our next generation mAb candidate for COVID-19, against the same contemporary viruses, and we also provided an update to ongoing structural analysis showing no meaningful mutational change in the pemivibart binding site since the Omicron shift late in 2021. In January 2025, March 2025 and August 2025, we announced continued neutralizing activity of PEMGARDA and VYD2311 against dominant SARS-CoV-2 variants XEC, LP.8.1 and XFG, respectively.

In addition to our COVID-19 programs, in November 2025, we announced the selection of VBY329, a potential best-in-class mAb candidate being developed for the prevention of RSV infections in neonates, infants and children. We expect to advance VBY329 toward IND readiness in the second half of 2026. Through our proprietary technology platform, we continue to investigate additional mAbs for protection and treatment of other important infectious diseases, such as measles. We are targeting identification of a preclinical mAb candidate for treatment and prevention of measles in the first half of 2026.

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"), WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"), to execute our chemistry, manufacturing and controls development, testing and clinical and commercial manufacturing activities. 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"), including Adimab's platform technology. 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 and through December 31, 2025, we have financed our operations primarily through the sale and issuance of preferred and common stock, including net proceeds of $464.7 million from sales of our preferred stock, net proceeds of $327.5 million from our initial public offering ("IPO"), net proceeds of $72.7 million from sales of our common stock under the Sales Agreement (as defined below) and net proceeds of $181.6 million from sales of our common stock and pre-funded warrants under the Underwriting Agreements (as defined below). We have also funded our operations from sales of PEMGARDA. 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 $52.5 million for the year ended December 31, 2025. As of December 31, 2025, we had an accumulated deficit of $954.5 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, 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, manufacturing activities, and commercialization efforts. Our expenses could increase substantially in connection with our ongoing activities, as we:

- continue to commercialize PEMGARDA;
- advance the development of VYD2311 and prepare for its potential commercial launch, if approved, as well as advance development of our other product candidates, such as VBY329;
- initiate and conduct clinical trials of our product candidates, including advancement of our REVOLUTION clinical program;
- develop product candidates in any new indications or patient populations;
- advance our preclinical and discovery programs, such as RSV and measles, including development and screening of additional antibodies, as well as engage in ongoing SARS-CoV-2 variant monitoring and testing;
- seek regulatory authorization or approval for any product candidates that successfully complete clinical trials;
- pursue 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 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.

As a result, 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 support our continuing operations and pursue our growth strategy. 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, 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 with 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 future 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 date of the consolidated financial statements in 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

Product Revenue, Net

In March 2024, we received EUA from the FDA for PEMGARDA. Product revenue, net consists of product revenue earned on the sales of PEMGARDA in the U.S. Product revenues are recognized net of variable consideration, including discounts and allowances, trade discounts and distributor fees, chargebacks, product returns and other incentives such as co-pay assistance programs.

Cost of Product Revenue

Cost of product revenue includes PEMGARDA manufacturing costs, labor and overhead costs, and stability study costs. PEMGARDA manufacturing costs include manufacturing materials, third-party manufacturing costs, packaging costs, shipping costs, and royalties.

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 any 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. We have also initiated discovery efforts to assess pipeline expansion beyond SARS-CoV-2, including the selection of a preclinical mAb candidate for the prevention of RSV and the advancement of early discovery programs targeting other potential targets such as measles. 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 candidate 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 advancing VYD2311 through clinical development, particularly as we advance the REVOLUTION clinical trial program, pursue EUA or regulatory approval of our product candidates, and continue to discover and develop additional product candidates.

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 obtain through collaborations, licenses or acquisitions;
- 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 pursuant to the relevant declaration under Section 564 of the FDCA. 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.

Through December 31, 2025, 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.

Other Income, Net

Other income, net consists of interest income earned from our cash and cash equivalents. 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, 2025, 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, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024:

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Change
Revenue:			
Product revenue, net	$ 53,426	$ 25,384	$ 28,042
Total revenue	53,426	25,384	28,042
Operating costs and expenses:			
Cost of product revenue	$ 3,747	$ 1,618	$ 2,129
Research and development	38,308	137,254	(98,946)
Selling, general and administrative	66,931	63,388	3,543
Total operating costs and expenses	108,986	202,260	(93,274)
Loss from operations	(55,560)	(176,876)	121,316
Other income:			
Other income, net	3,071	6,951	(3,880)
Total other income, net	3,071	6,951	(3,880)
Net loss	$ (52,489)	$ (169,925)	$ 117,436

The following discussion presents the components of our expenses for the periods presented:

Product Revenue, Net

Product revenue, net was $53.4 million and $25.4 million for the years ended December 31, 2025 and 2024, respectively. The $28.0 million increase is primarily the result of increased product sales in 2025 following the launch of PEMGARDA in the second quarter of 2024.

Cost of Product Revenue

Cost of product revenue was $3.7 million and $1.6 million for the years ended December 31, 2025 and 2024, respectively. The $2.1 million increase is the result of sales related to PEMGARDA due to an increase in product demand and certain period costs.

We began capitalizing our inventory costs in March 2024, in connection with EUA from the FDA and based upon our expectation that these costs would be recoverable through commercialization of PEMGARDA. Prior to the capitalization of our inventory costs, such costs were recorded as research and development expenses in the period incurred. Had our pre-EUA manufacturing costs been capitalized, our reported margins would approach 80%.

Research and Development Expenses

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Change
Direct, external research and development expenses by program:			
Pemivibart[1]	$ 3,140	$ 31,757	$ (28,617)
VYD2311[2]	4,597	67,505	(62,908)
VBY329[3]	615	—	615
Early-stage programs	428	974	(546)
Unallocated research and development expenses:			
Personnel related (including stock-based compensation)	14,783	21,274	(6,491)
External discovery-related and other costs[4]	14,745	15,744	(999)
Total research and development expenses	$ 38,308	$ 137,254	$ (98,946)

[1] In March 2023, we announced the nomination of VYD222 (pemivibart) 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] In November 2025, we announced the nomination of VBY329 as an RSV mAb candidate for preclinical development.
[4] Included in External discovery-related and other costs are expenses associated with adintrevimab which were historically presented in the direct, external research and development expense by program section.

Research and development expenses were $38.3 million for the year ended December 31, 2025, compared to $137.3 million for the year ended December 31, 2024. The $99.0 million decrease in research and development expenses was primarily due to the following:

- Decrease in direct costs related to our pemivibart program resulted from decrease of $13.7 million in contract research costs for our Phase 3 CANOPY clinical trial, $12.8 million in contract costs for commercial manufacturing, $1.4 million in nonclinical costs and $0.7 million in other external costs;
- Decrease in direct costs related to our VYD2311 program resulted from decrease of $62.1 million in contract costs for clinical and commercial manufacturing and $1.8 million in nonclinical expenses, partially offset by increase of $0.6 million in clinical trial costs and $0.4 million in external discovery-related and other costs;
- Increase in direct costs for our VBY329 program resulted from the nomination of VBY329 as an RSV mAb candidate in the fourth quarter of 2025, with costs resulting from $0.4 million in external discovery costs, as well as $0.2 million in nonclinical expense;
- Decrease in direct costs related to our early-stage programs resulted from decrease of $0.9 million in contract development and manufacturing costs, partially offset by an increase of $0.3 million in external discovery-related and other costs;
- Decrease in personnel related costs resulted from decrease of $6.5 million in headcount-related costs; and
- Decrease in external discovery-related and other costs resulted from decrease of $1.2 million in other external costs and $0.4 million in nonclinical costs, partially offset by an increase of $0.5 million in contract manufacturing and $0.1 million in clinical trial expenses.

Acquired In-Process Research and Development ("IPR&D") Expenses

There was no IPR&D expense recognized for the years ended December 31, 2025 and 2024.

Selling, General and Administrative Expenses

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024	Change
Personnel-related costs	$ 31,256	$ 29,909	$ 1,347
Professional and consultant fees	29,698	29,773	(75)
Other	5,977	3,706	2,271
Total selling, general and administrative expenses	$ 66,931	$ 63,388	$ 3,543

Selling, general and administrative expenses were $66.9 million for the year ended December 31, 2025, compared to $63.4 million for the year ended December 31, 2024. The $3.5 million increase in selling, general and administrative expenses was primarily due to the following:

- Increase in personnel-related costs was primarily due to an increase in headcount-related costs of $7.5 million, partially offset by a decrease in stock-based compensation expense of $6.2 million. The decrease in stock-based compensation expense was primarily due to stock-based compensation expense recognized in 2024 associated with the accelerated vesting of a portion of the outstanding stock options granted to our former Chief Executive Officer, in accordance with the terms of his employment agreement;
- Decrease in professional and consultant fees resulted from decrease of $0.6 million in sales and marketing costs and $0.5 million in insurance costs, partially offset by increase of $1.0 million in professional services fees; and
- Increase in other costs primarily resulted from increase of $0.9 million in conference related costs and $1.2 million in other employee related travel expense.

Other Income

Other income was $3.1 million and $7.0 million for the years ended December 31, 2025 and 2024, respectively, consisting primarily of interest earned on our invested cash balances.

Liquidity and Capital Resources

Sources of Liquidity

Through December 31, 2025, we have incurred significant operating losses and negative cash flows from operations. Although we received an EUA from the FDA for PEMGARDA in March 2024, we may continue to incur significant expenses and potential operating losses for the foreseeable future as we continue to commercialize PEMGARDA and advance the development of VYD2311, VBY329, and our other product candidates. As of December 31, 2025, we have financed our operations primarily with net proceeds of $464.7 million from sales of our preferred stock, $327.5 million from our IPO in August 2021, $72.7 million from sales of our common stock under the Sales Agreement (as defined below), and $181.6 million from sales of our common stock and pre-funded warrants under the Underwriting Agreements (as defined below). After receiving EUA in March 2024, we have also funded our operations from sales of PEMGARDA.

As of December 31, 2025, we had cash and cash equivalents of $226.7 million.

Shelf Registration Statements

In September 2022, we filed a shelf registration statement on Form S-3 with the SEC and an 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 our securities (the "2022 Shelf Registration Statement"). The 2022 Shelf Registration Statement expired upon the effectiveness of the 2025 Shelf Registration Statement (as defined below).

In October 2025, we filed a new shelf registration statement on Form S-3 with the SEC and an accompanying base prospectus, which was declared effective by the SEC on December 23, 2025, for the offer and sale of up to $350 million of our securities (the "2025 Shelf Registration Statement"). As of December 31, 2025, excluding the $75 million allocated to the 2025 ATM Prospectus Supplement (as defined below), $275 million of our securities remained available for offer and sale under the 2025 Shelf Registration Statement.

Sales Agreement

In December 2023, we entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor") and filed with the SEC a prospectus supplement to the 2022 Shelf Registration Statement (the "2023 ATM Prospectus Supplement"), pursuant to which we could, 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 of 1933, as amended (the "Securities Act"). Cantor was entitled to a commission of 3% of the gross proceeds from any sales of such shares. In 2024, we sold 9,000,000 shares of our common stock under the Sales Agreement and 2023 ATM Prospectus Supplement at an average price of $4.50 per share for $39.3 million in proceeds net of commissions. In 2025, we sold 23,055,402 shares of our common stock under the Sales Agreement and 2023 ATM Prospectus Supplement at an average price of $1.49 per share for $33.4 million in proceeds net of commissions. Upon the effectiveness of the 2025 Shelf Registration Statement, all offers and sales under the 2023 ATM Prospectus Supplement were deemed terminated.

In October 2025, in connection with the filing of the 2025 Shelf Registration Statement, we filed with the SEC a new prospectus supplement (the "2025 ATM Prospectus Supplement"), 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. The 2025 Shelf Registration Statement was declared effective by the SEC on December 23, 2025. As of December 31, 2025, $75.0 million remained available for sale under the 2025 ATM Prospectus Supplement.

Underwriting Agreements

In August 2025, we completed an underwritten public offering pursuant to an underwriting agreement (the "August Underwriting Agreement") with Cantor, as representative of the underwriters named therein, pursuant to which we issued and sold an aggregate of 89,234,480 shares of our common stock at a price of $0.52 per share, and pre-funded warrants to purchase up to an aggregate of 21,342,442 shares of common stock at a price of $0.5199 per pre-funded warrant. The price of

$0.5199 per pre-funded warrant represented the $0.52 per share purchase price for the common stock less the exercise price of $0.0001 per pre-funded warrant. The pre-funded warrants are exercisable at any time after their original issuance and will not expire. We received total net proceeds of approximately $53.5 million, after deducting underwriting discounts and commissions and offering expenses.

In November 2025, we completed an underwritten public offering pursuant to an underwriting agreement (the "November Underwriting Agreement" and together with the August Underwriting Agreement, the "Underwriting Agreements") with Cantor, as representative of the underwriters named therein, pursuant to which we issued and sold an aggregate of 44,000,000 shares of our common stock at a price of $2.50 per share, and pre-funded warrants to purchase up to an aggregate of 6,000,000 shares of common stock at a price of $2.4999 per pre-funded warrant (the "November 2025 Underwritten Public Offering"). The price of $2.4999 per pre-funded warrant represented the $2.50 per share purchase price for the common stock less the exercise price of $0.0001 per pre-funded warrant. The pre-funded warrants are exercisable at any time after their original issuance and will not expire. We received total net proceeds of approximately $117.2 million, after deducting underwriting discounts and commissions and offering expenses.

In December 2025, and in connection with the November 2025 Underwritten Public Offering, Cantor exercised the option pursuant to the November Underwriting Agreement to purchase 4,675,000 additional shares of common stock at the public offering price of $2.50, less underwriting discounts and commissions. In connection with such exercise, we received total net proceeds of approximately $10.9 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

Loan Agreement

On April 18, 2025, we entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, as lender (the "Lender"). The Loan Agreement provides for a senior secured term loan facility in an aggregate principal amount of up to $30 million (the "Term Facility") consisting of (a) Term A Loans in an aggregate principal amount of up to $10 million, which shall be available to be drawn from and after August 15, 2025 through December 31, 2026 upon compliance with certain financial covenants and conditions, (b) Term B Loans in an aggregate principal amount of up to $10 million, which shall be available to be drawn during the period commencing on the date of the achievement of certain net product revenue milestones and ending on June 30, 2027, and (c) Term C Loans in an aggregate principal amount of up to $10 million, which shall be available to be drawn during the period commencing on the date of the achievement of certain net product revenue milestones and ending on June 30, 2027. The proceeds of the Term Facility may be used for working capital and general business purposes. As of December 31, 2025, we had not satisfied certain financial covenants and conditions, including the net product revenue milestone required to be eligible to access proceeds from the Term Facility. Accordingly, as of December 31, 2025, no amounts have been drawn down under the Loan Agreement.

The loans under the Term Facility are due and payable on March 1, 2029 and bear interest that is payable monthly, commencing with the month in which any loans are funded under the Term Facility, in arrears at a per annum rate, subject to increase during an Event of Default (as defined in the Loan Agreement), equal to the greater of (x) the Wall Street Journal prime rate minus 0.25%, subject to a 9.00% cap, and (y) 6.00%. Commencing on April 1, 2027, which date may be extended to April 1, 2028 upon the achievement of certain net product revenue milestones (the "Interest-Only Period Extension"), we will be required to repay the principal of the Term Facility in 24 consecutive equal monthly installments or, in the case of the Interest-Only Period Extension, 12 consecutive equal monthly installments. At maturity, or if earlier prepaid, we will also be required to pay a final payment fee equal to 4.50% of the aggregate principal amount of the loans advanced under the Term Facility. The Loan Agreement provides for an unused term loan commitment fee equal to 1.00% of the Term Facility upon the earliest to occur of (a) July 1, 2027, (b) the occurrence of an Event of Default under the Loan Agreement and (c) the termination of the Loan Agreement; provided, that such fee will be waived by the Lender in the event that we have requested and the Lender has funded any loans under the Term Facility prior to such date.

Cash Flows

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

(in thousands)	Year Ended December 31, 2025	Year Ended December 31, 2024
Net cash used in operating activities	$ (58,135)	$ (170,491)
Net cash used in investing activities	(155)	(140)
Net cash provided by financing activities	215,630	39,331
Effect of exchange rate changes on cash and cash equivalents	—	8
Net increase (decrease) in cash and cash equivalents	$ 157,340	$ (131,292)

Operating Activities

During the year ended December 31, 2025, operating activities used $58.1 million of cash, primarily due to our net loss of $52.5 million and changes in our operating assets and liabilities of $19.6 million, partially offset by non-cash charges of $14.0 million. The changes in our operating assets and liabilities primarily consisted of a $30.8 million decrease in accrued expenses, a $3.3 million increase in accounts receivable, a $1.2 million decrease in operating lease liabilities, and a $0.4 million increase in inventory, partially offset by a $12.9 million decrease in prepaid expenses and a $3.2 million increase in accounts payable. The decrease in accrued expenses was primarily due to the timing of vendor invoicing and payments. The decrease in prepaid expenses and other current assets was primarily due to the utilization of WuXi Biologics manufacturing credits.

During the year ended December 31, 2024, operating activities used $170.5 million of cash, primarily due to our net loss of $169.9 million and changes in our operating assets and liabilities of $23.5 million, partially offset by non-cash charges of $22.9 million. The changes in our operating assets and liabilities primarily consisted of a $24.9 million increase in inventory, a $10.9 million increase in accounts receivable, a $1.7 million decrease in operating lease liabilities, and a $0.7 million decrease in other non-current liabilities, partially offset by a $9.0 million increase in accrued expenses, a $3.2 million decrease in prepaid expenses, a $2.4 million increase in accounts payable, and a $0.1 million decrease in other non-current assets. The increase in accrued expenses was primarily due to the timing of vendor invoicing and payments. The decrease in prepaid expenses and other current assets was primarily due to the utilization of WuXi Biologics manufacturing prepayments.

Investing Activities

Net cash used in investing activities during the years ended December 31, 2025 and 2024 consisted of $0.2 million and $0.1 million, respectively, in purchases of property and equipment.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2025 consisted of $182.5 million from the issuance of common stock and pre-funded warrants sold under the Underwriting Agreements, $33.4 million from the issuance of common stock under the Sales Agreement, $0.4 million from exercises of stock options, and $0.2 million from issuances of common stock under our employee stock purchase plan, partially offset by $0.6 million in payments for offering costs related to the Underwriting Agreements and $0.3 million in payments for offering costs related to the Sales Agreement.

Net cash provided by financing activities during the year ended December 31, 2024 consisted of $39.3 million from the issuance of common stock under the Sales Agreement, $0.4 million from exercises of stock options, and $0.2 million from issuances of common stock under our employee stock purchase plan, partially offset by $0.6 million in payments for offering costs related to the Sales Agreement.

Funding Requirements

Our expenses could increase in connection with our ongoing activities, particularly as we advance the REVOLUTION clinical program, our nonclinical and preclinical studies, and the clinical trials of our other product candidates, our ongoing and planned commercialization efforts, and any associated manufacturing activities in connection with our clinical

development and commercialization activities. 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 scope, progress, results and costs of discovery, nonclinical studies, preclinical development, laboratory testing and clinical trials for our product candidates and associated development programs, including our REVOLUTION clinical program;
- 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 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 future 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.

We expect to finance our operations 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 support our continuing operations and pursue our growth strategy. 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. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. 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

Manufacturing Commitments

In July 2020, we entered into a clinical Master Services Agreement with WuXi Biologics, which was amended in March 2026 (as amended, the "Clinical Master Services Agreement"). The Clinical Master Services Agreement outlines the terms and conditions under which WuXi Biologics coordinates biologics development and clinical manufacturing services for us.

In December 2020, we entered into a Commercial Manufacturing Services Agreement with WuXi Biologics, which was amended and restated in August 2021, further amended and restated in September 2023 and amended in March 2026 (as amended and restated and subsequently amended, 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.

Through December 31, 2025, we committed to noncancelable purchase obligations related to commercial drug substance and drug product manufacturing under the Commercial Manufacturing Agreement. As of December 31, 2025, the total remaining contractually binding commercial drug substance and drug product purchase obligations due to WuXi Biologics was $10.6 million, which was included in accounts payable and accrued expenses. The remaining contractually binding purchase obligation was paid in January 2026.

Through December 31, 2025, we committed to noncancelable purchase obligations related to the procurement of materials to be used in future drug substance and drug product manufacturing under the Commercial Manufacturing Agreement. As of December 31, 2025, the total remaining contractually binding purchase obligations due to WuXi Biologics was $3.5 million, which was included in accrued expenses. The remaining contractually binding purchase obligation was paid in January 2026.

Operating Lease Commitments

In September 2021, we entered into a five-year facilities lease agreement for approximately 9,600 square feet of office space in Waltham, Massachusetts, which provided for monthly rental payments, including base rent charges of $0.4 million per year, subject to periodic rent increases, and our proportionate share of operating expenses. We exercised our option to terminate and this lease agreement expired in accordance with its terms on May 31, 2025.

In June 2022, we entered into a two-year noncancelable agreement for dedicated laboratory and office space in Newton, Massachusetts (the "Newton, MA Lease"), which was amended in September 2022. Pursuant to the amended Newton, MA Lease, we entered into a two-year noncancelable agreement for new dedicated laboratory and office space in Newton, Massachusetts, on the same campus as, and in lieu of, the space leased under the original lease. We took occupancy of the new dedicated laboratory and office space in December 2022. The amended Newton, MA Lease provided for monthly rental payments, including base rent charges of $1.3 million per year. In August 2024 and May 2025, the Newton, MA Lease was further amended to extend the lease through December 2027, with an option to further extend the lease for an additional twenty-four months or continue the lease on a month-to-month basis after completion of the term ending in December 2027.

In February 2026, we further amended the Newton, MA Lease to add additional dedicated laboratory space which commenced on March 1, 2026. The amendment provides for incremental annual base rent of $0.3 million for the remainder of the lease term, through December 2027. As the modification had not commenced as of December 31, 2025, no right-of-use asset or lease liability has been recorded in the accompanying financial statements.

In January 2026, we entered into an agreement to lease approximately 33,000 square feet of office space in New Haven, Connecticut. The term of the lease will commence after the later of (i) the date on which landlord improvements to the premises are deemed to be substantially completed, or (ii) the delivery of the lender consent package. The lease has an initial term of one hundred twenty-nine months, measured from the lease commencement date. Our obligation for the payment of rent for the premises begins six months after the lease commencement date and total future minimum lease payments are expected to be $10.9 million. The lease includes a tenant improvement allowance of approximately $1.0 million.

The New Haven, CT lease requires us to provide a security deposit of $1.0 million in the form of a letter of credit, which will be reduced by 50% following the first twelve months of rent payments.

As the New Haven, CT lease had not commenced as of December 31, 2025, no right-of-use asset or lease liability has been recorded in the accompanying financial statements.

Future minimum lease payments under the noncancelable leases as of December 31, 2025 were as follows (in thousands):

Year Ending December 31,	Operating Lease
2026	$ 1,320
2027	$ 1,320
Total lease payments	2,640
Present value adjustment	(146)
Present value of operating lease liability	$ 2,494

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 for a product under the cell line license agreement, no royalties would be owed by us to WuXi Biologics for net sales of such a licensed product. We have an option to buy out our royalty obligations by making a one-time payment in the low eight-figures to WuXi Biologics with respect to certain licensed products or middle-seven figures with respect to certain other licensed products. 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, 2025. 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. During the year ended December 31, 2025, we expensed $2.1 million of royalties, while reserving all rights under the Adimab Assignment Agreement and the applicable law. 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. 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 years ended December 31, 2025 and 2024, we were not obligated to pay any option exercise fee, a drug delivery fee, or optimization completion 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.

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, and the reported amounts of revenues and 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.

Revenue Recognition

We recognize revenue in accordance with ASC Topic 606 - Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when or as performance obligations are satisfied by transferring control of promised goods or services to the customer, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. At contract inception, we assess the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

Following EUA from the FDA in March 2024, we began generating product revenue from sales of PEMGARDA in April 2024.

We sell PEMGARDA in the United States primarily to third-party specialty distributors and directly to a small number of infusion centers, healthcare providers and provider institutions. Revenue is recognized when or as performance obligations are satisfied by transferring control of promised goods to a customer, generally upon delivery, based on an amount that reflects the consideration to which we expected to be entitled.

Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Discounts and Allowances

We record reserves, based on contractual terms, for the following components of variable consideration related to product sold during the reporting period, as well as our estimate of product that remains in the distribution channel inventory of our customers at the end of the reporting period, if applicable. On a quarterly basis, we update our estimates, if necessary, and record any material adjustments in the period they are identified.

Trade Discounts, Group Purchase Organization and Distributor Fees

We provide customary discounts on PEMGARDA sales for prompt payment, the terms of which are explicitly stated in our contracts. We also pay fees to specialty distributors for sales order management, data, and distribution services, as well as fees to group purchasing organizations ("GPO") for administrative services, the terms of which are also explicitly stated in our contracts. Such fees are not for a distinct good or service and, accordingly, are recorded as a reduction of revenue, as well as a reduction to accounts receivable (trade discounts) or as a component of accrued expenses (distributor and GPO fees).

Chargebacks

We are subject to discount obligations under our contract with the U.S. Department of Veterans Affairs and GPOs where pricing on PEMGARDA is extended below wholesaler list price to participating entities and GPO members. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included as a component of accrued expenses.

Product Returns

We offer a right of return for purchased units of PEMGARDA for damage, defect, recall, and/or product expiry, provided the product expiry is within a specified period as set forth in our return goods policy. We estimate the amount of product sales that will be returned using quantitative and qualitative considerations. Reserves for estimated returns are recorded as a reduction of product revenue in the period that the related revenue is recognized, as well as a component of accrued expenses.

Other Incentives

Other incentives include a co-pay assistance program for eligible patients with commercial insurance in the U.S. The co-pay assistance program assists certain commercially insured patients by reducing each participating patient's financial responsibility for the purchase price, up to a specified dollar amount of assistance.

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. 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, 2025. 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 December 31, 2026. 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 December 31, 2026. 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 on page F-1 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 Financial Officer (our principal executive officer and principal financial officer), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act as amended, 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 officer, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. 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 the evaluation of our disclosure controls and procedures as of December 31, 2025, our Chief 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). Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. 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, 2025, 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, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Cell Line License Agreement

Effective March 4, 2026, we entered into Amendment No. 3 (the "Cell Line License Agreement Amendment") to the Cell Line License Agreement, dated December 2, 2020 and previously amended as of February 2, 2023 and March 13, 2024 (as amended, the "Cell Line License Agreement"), by and between us and WuXi Biologics (Hong Kong) Limited ("WuXi Biologics"). The Cell Line License Agreement Amendment amended the Cell Line License Agreement to provide that we have an option to buy out our 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 with respect to certain licensed products and by making a one-time payment in the middle seven-figures to WuXi Biologics with respect to certain other licensed products. Also, the Cell Line License Agreement Amendment provides for a waiver of our royalty obligations to WuXi Biologics to the extent derived or arising from a licensed product sold in the U.S. if our ability to have such licensed product manufactured by WuXi Biologics or its affiliates becomes materially restricted due to certain government actions, including but not limited to a law, rule, regulation, guideline or order that materially prevents us from being able to enter into or maintain a contract with a governmental entity, or from receiving grant funds from such entity, or materially affects our ability to obtain government insurance coverage of such licensed product, with such waiver continuing for so long as such government action continues.

The foregoing summary of the terms of the Cell Line License Agreement Amendment does not purport to be a complete description of the rights and obligations of the parties thereunder, and is qualified in its entirety by reference to the Cell Line License Agreement Amendment, which will be filed as an exhibit to our Quarterly Report on Form 10-Q to be filed with the Securities and Exchange Commission for the fiscal quarter ending March 31, 2026.

Clinical Master Services Agreement

Effective March 4, 2026, we entered into Amendment No. 1 (the "Clinical Manufacturing Agreement Amendment") to the Master Services Agreement, dated July 21, 2020 (the "Clinical Manufacturing Agreement"), by and between us and WuXi Biologics. The Clinical Manufacturing Agreement Amendment amended the Clinical Manufacturing Agreement to provide that the term of the Clinical Manufacturing Agreement shall expire on March 1, 2036, subject to renewal for periods to be agreed by the parties. The Clinical Manufacturing Agreement Amendment also provides that we may terminate the Clinical Manufacturing Agreement, effective immediately, if any new or existing law, rule, regulation, guideline or order materially prevents us from being able to enter into or maintain a contract with a U.S. governmental entity, or from receiving grant funds from such entity, or materially affects our ability to obtain government insurance coverage of any product under the Clinical Manufacturing Agreement, in each case, as a result of WuXi Biologics providing services to us under the

Clinical Manufacturing Agreement or being a party to the Clinical Manufacturing Agreement. Additionally, the Clinical Manufacturing Agreement Amendment also incorporates certain technology transfer and intellectual property obligations for WuXi Biologics.

The foregoing summary of the terms of the Clinical Manufacturing Agreement Amendment does not purport to be a complete description of the rights and obligations of the parties thereunder, and is qualified in its entirety by reference to the Clinical Manufacturing Agreement Amendment, which will be filed as an exhibit to our Quarterly Report on Form 10-Q to be filed with the Securities and Exchange Commission for the fiscal quarter ending March 31, 2026.

Commercial Manufacturing Agreement

Effective March 4, 2026, we entered into Amendment No. 1 (the "Commercial Manufacturing Agreement Amendment") to the Second Amended and Restated Commercial Manufacturing Services Agreement, dated September 19, 2023 (the "Commercial Manufacturing Agreement"), by and between us and WuXi Biologics. The Commercial Manufacturing Agreement Amendment amended the Commercial Manufacturing Agreement to provide that the term of the Commercial Manufacturing Agreement shall expire on March 1, 2036, subject to renewal for periods to be agreed by the parties. The Commercial Manufacturing Agreement Amendment also provides that we may terminate the Commercial Manufacturing Agreement, effective immediately, if any new or existing law, rule, regulation, guideline or order materially prevents us from being able to enter into or maintain a contract with a U.S. governmental entity, or from receiving grant funds from such entity, or materially affects our ability to obtain government insurance coverage of any product under the Commercial Manufacturing Agreement, in each case, as a result of WuXi Biologics providing services to us under the Commercial Manufacturing Agreement or being a party to the Commercial Manufacturing Agreement. Additionally, the Commercial Manufacturing Agreement Amendment provides that we may terminate the Commercial Manufacturing Agreement for convenience, with advance notice, and incorporates certain technology transfer obligations for WuXi Biologics.

The foregoing summary of the terms of the Commercial Manufacturing Agreement Amendment does not purport to be a complete description of the rights and obligations of the parties thereunder, and is qualified in its entirety by reference to the Commercial Manufacturing Agreement Amendment, which will be filed as an exhibit to our Quarterly Report on Form 10-Q to be filed with the Securities and Exchange Commission for the fiscal quarter ending March 31, 2026.

Trading Plans

During the three months ended December 31, 2025, none of our directors or officers 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 2026 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. Exhibits 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).
4.4	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on August 22, 2025).
4.5	Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K (File No. 001-40703), filed with the Securities and Exchange Commission on November 19, 2025).
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, as amended, 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*+	2026 Inducement Plan and Forms of Stock Option Grant Notice, Stock Option Agreement, Exercise Notice, RSU Award Grant Notice and RSU Award Agreement.
10.5*+	Form of Indemnification Agreement with Executive Officers and Directors.
10.6+	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).

10.7*+	First Amendment to the Employment Agreement of Jill Andersen, by and between the Registrant and Jill Andersen, dated January 31, 2026.
10.8+	Employment Agreement by and between the Registrant and Robert Allen, dated March 14, 2023 (incorporated by reference to Exhibit 10.12 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 28, 2024).
10.9*+	First Amendment to the Employment Agreement of Robert Allen, by and between the Registrant and Robert Allen, dated January 31, 2026.
10.10+	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).
10.11*+	First Amendment to the Employment Agreement of William Duke, Jr., by and between the Registrant and William Duke, Jr., dated January 31, 2026.
10.12+#	Employment Agreement by and between the Registrant and Julie Green, dated January 24, 2024 (incorporated by reference to Exhibit 10.14 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 28, 2024).
10.13+	First Amendment to the Employment Agreement of Julie Green, by and between the Registrant and Julie Green, dated October 23, 2024 (incorporated by reference to Exhibit 10.15 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 20, 2025).
10.14*+	Second Amendment to the Employment Agreement of Julie Green, by and between the Registrant and Julie Green, dated January 31, 2026.
10.15+#	Employment Agreement by and between the Registrant and Timothy Lee, dated May 30, 2024 (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 20, 2025).
10.16*+	First Amendment to the Employment Agreement of Timothy Lee, by and between the Registrant and Timothy Lee, dated January 31, 2026.
10.17+	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).
10.18†#	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).
10.19†#	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).
10.20†	Amendment Number One to the Collaboration Agreement by and between the Registrant and Adimab, LLC, dated 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).
10.21†	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).
10.22†#	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).
10.23†#	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).
10.24†	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).
10.25†	Amendment No. 2 to the Cell Line License Agreement by and between the Registrant and WuXi Biologics (Hong Kong) Limited, dated March 13, 2024 (incorporated by reference to Exhibit 10.23 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 28, 2024).

10.26†	Clinical Master Services Agreement by and 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).
10.27	Controlled Equity Offering℠ 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).
10.28†	Loan and Security Agreement by and between the Registrant and Silicon Valley Bank, a Division of First-Citizens Bank & Trust Company, dated April 18, 2025 (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 April 21, 2025).
19.1*	Insider Trading Prevention Policy of the Registrant.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer and 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 and 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 (incorporated by reference to Exhibit 97.1 of the Registrant's Annual Report on Form 10-K (File No. 001-40703), filed with the Securities and Exchange Commission on March 28, 2024).
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 5, 2026

By: /s/ William Duke, Jr.

William Duke, Jr.
Chief Financial Officer
(Principal Executive Officer, Principal Financial Officer and Principal Accounting 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.

Name	Title	Date
/s/ William Duke, Jr. William Duke, Jr.	Chief Financial Officer *(Principal Executive Officer, Principal Financial Officer and Principal Accounting Officer)*	March 5, 2026
/s/ Marc Elia Marc Elia	Chairman of the Board of Directors	March 5, 2026
/s/ Tamsin Berry Tamsin Berry	Director	March 5, 2026
/s/ Paul B. Bolno, M.D. Paul B. Bolno, M.D.	Director	March 5, 2026
/s/ Terrance McGuire Terrance McGuire	Director	March 5, 2026
/s/ Kevin F. McLaughlin Kevin F. McLaughlin	Director	March 5, 2026
/s/ Ajay Royan Ajay Royan	Director	March 5, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Invivyd, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity 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, 2025 and 2024, 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 5, 2026

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, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 226,689	$ 69,349
Accounts receivable, net[1]	13,919	10,906
Prepaid expenses and other current assets	6,859	20,426
Total current assets	247,467	100,681
Inventory	25,499	25,907
Property and equipment, net	1,365	1,508
Operating lease right-of-use assets	2,442	1,385
Other non-current assets	110	34
Total assets	$ 276,883	$ 129,515
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 13,744	$ 10,448
Accrued expenses [2]	19,053	50,197
Operating lease liabilities	1,314	1,304
Other current liability	52	27
Total current liabilities	34,163	61,976
Operating lease liabilities, non-current	1,180	—
Total liabilities	35,343	61,976
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock (undesignated), $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized, 281,987,033 shares issued and outstanding at December 31, 2025; 119,835,162 shares issued and outstanding at December 31, 2024	28	12
Additional paid-in capital	1,196,036	969,526
Accumulated other comprehensive loss	(41)	(5)
Accumulated deficit	(954,483)	(901,994)
Total stockholders' equity	241,540	67,539
Total liabilities and stockholders' equity	$ 276,883	$ 129,515

(1) Includes an allowance for doubtful accounts of $323 and $0 for the years ended December 31, 2025 and 2024, respectively.

(2) Includes related-party amounts of $703 and $1,274 for the years ended December 31, 2025 and 2024, respectively (see Note 15).

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, 2025	Year Ended December 31, 2024
Revenue:		
Product revenue, net	$ 53,426	$ 25,384
Total revenue	53,426	25,384
Operating costs and expenses:		
Cost of product revenue[(1)]	3,747	1,618
Research and development[(2)]	38,308	137,254
Selling, general and administrative	66,931	63,388
Total operating costs and expenses	108,986	202,260
Loss from operations	(55,560)	(176,876)
Other income:		
Other income, net	3,071	6,951
Total other income, net	3,071	6,951
Net loss	(52,489)	(169,925)
Other comprehensive income (loss)		
Unrealized (loss) gain, net of tax	(36)	8
Comprehensive loss	$ (52,525)	$ (169,917)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.30)	$ (1.43)
Weighted-average common shares outstanding, basic and diluted	172,212,902	118,555,073

(1) Includes related-party amounts of $2,137 and $1,027 for the years ended December 31, 2025 and 2024, respectively (see Note 15).

(2) Includes related-party amounts of $4,557 and $4,546 for the years ended December 31, 2025 and 2024, respectively (see Note 15).

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

INVIVYD, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2024	119,835,162	$ 12	—	$ —	$ 969,526	$ (5)	$ (901,994)	67,539
Stock-based compensation expense	—	—	—	—	11,643	—	—	11,643
Exercise of stock options	292,273	—	—	—	411	—	—	411
Issuance of common stock upon restricted stock units vesting	561,000	—	—	—	—	—	—	—
Common stock issued in connection with at-the-market offering, net	23,055,402	2	—	—	32,544	—	—	32,546
Pre-funded warrants issued in connection with public offering, net	—	—	—	—	26,095	—	—	26,095
Common stock issued in connection with public offering, net	137,909,480	14	—	—	155,563	—	—	155,577
Issuance of common stock under the employee stock purchase plan	333,716		—	—	254	—	—	254
Unrealized loss, net of tax	—	—	—	—	—	(36)	—	(36)
Net loss	—	—	—	—	—	—	(52,489)	(52,489)
Balances at December 31, 2025	281,987,033	28	—	—	1,196,036	(41)	(954,483)	241,540

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

INVIVYD, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share amounts)

	Common Stock		Treasury Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balances at December 31, 2023	110,160,684	$ 11	—	$ —	$ 909,539	$ (13)	$ (732,069)	$ 177,468
Stock-based compensation expense	—	—	—	—	20,288	—	—	20,288
Issuance of common stock, net of issuance costs	9,000,000	1	—	—	39,056	—	—	39,057
Exercise of stock options	468,355				420			420
Issuance of common stock under the employee stock purchase plan	206,123	—	—	—	223	—	—	223
Unrealized gain, net of tax	—	—	—	—	—	8	—	8
Net loss	—	—	—	—	—	—	(169,925)	(169,925)
Balances at December 31, 2024	119,835,162	12	—	—	969,526	(5)	(901,994)	67,539

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

INVIVYD, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31, 2025	Year Ended December 31, 2024
Cash flows from operating activities:		
Net loss	$ (52,489)	$ (169,925)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	11,643	19,788
Amortization of operating lease right-of-use assets	1,352	1,647
Depreciation and amortization expense	755	1,466
Other non-cash adjustments	298	—
Changes in operating assets and liabilities:		
Accounts receivable	(3,337)	(10,906)
Inventory	(373)	(24,889)
Prepaid expenses and other current assets	12,924	3,185
Other non-current assets	(77)	141
Accounts payable	3,211	2,423
Accrued expenses	(30,847)	8,950
Operating lease liabilities	(1,218)	(1,663)
Other current liabilities	23	(8)
Other non-current liabilities	—	(700)
Net cash used in operating activities	(58,135)	(170,491)
Cash flows from investing activities:		
Purchases of property and equipment	(155)	(140)
Net cash used in investing activities	(155)	(140)
Cash flows from financing activities:		
Proceeds from exercises of stock options	411	420
Proceeds from issuance of common stock under the employee stock purchase plan	254	223
Proceeds from at-the-market offering, net of commissions	33,400	39,285
Proceeds from underwritten public offering, net of underwriting discounts and commissions	182,534	—
Payments for at-the-market offering costs	(336)	(597)
Payments for underwritten public offering costs	(633)	—
Net cash provided by financing activities	215,630	39,331
Effect of exchange rate changes on cash and cash equivalents	—	8
Net increase (decrease) in cash and cash equivalents	157,340	(131,292)
Cash and cash equivalents at beginning of period	69,349	200,641
Cash and cash equivalents at end of period	$ 226,689	$ 69,349
Supplemental disclosure of cash flow information		
Deferred offering costs in accrued expenses	$ 171	$ —
Deferred offering costs in accounts payable	$ 88	$ 71
Property and equipment included in accrued expenses	$ 206	$ —
Property and equipment included in accounts payable	$ 33	$ —

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

1. Nature of the Business and Basis of Presentation

Invivyd, Inc. (the "Company") is a biopharmaceutical company focused on the discovery, development and commercialization of monoclonal antibody ("mAb") therapies for the prevention and treatment of serious viral infectious diseases, beginning with SARS-CoV-2, the virus that causes COVID-19, and expanding into other high-need indications, such as respiratory syncytial virus ("RSV") and measles.

On March 22, 2024, the Company received emergency use authorization ("EUA") from the U.S. Food and Drug Administration ("FDA") for PEMGARDA 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.

In January 2024, the Company nominated VYD2311, a next generation mAb candidate for COVID-19, as a drug candidate. VYD2311 is a mAb with high *in vitro* neutralization potency shown against prominent SARS-CoV-2 variants tested to date. In October 2025, the Company announced that the FDA cleared the Company's its Investigational New Drug ("IND") application for VYD2311 and provided feedback to advance the Company's REVOLUTION clinical program, Invivyd's development program for VYD2311. The REVOLUTION clinical program includes two clinical trials, DECLARATION and LIBERTY. In December 2025, the Company initiated DECLARATION, which is a Phase 3 randomized, triple-blind, placebo-controlled clinical trial to evaluate VYD2311 safety and efficacy in prevention of symptomatic, RT-PCR-confirmed COVID-19 at three months, with either a single dose or monthly doses of VYD2311, each administered via intramuscular injection, compared to placebo. DECLARATION is designed to support potential Biologics License Application ("BLA") submission, with top-line data anticipated in mid-2026. In February 2026, the Company announced alignment with the FDA on LIBERTY, which is designed as a Phase 3, randomized, double-blind clinical trial to evaluate the safety, serum virus neutralizing antibody responses, and pharmacokinetics of (1) VYD2311, (2) an mRNA COVID vaccine, and (3) co-administered VYD2311 with an mRNA COVID vaccine. The FDA has granted "Fast Track" designation for VYD2311 for the prevention of COVID-19 in individuals with underlying risk factors for progression to severe disease. Fast Track designation is a process designed to facilitate the development and expedite the regulatory review of drugs to treat serious conditions and fill an unmet medical need, including eligibility for priority review and rolling review of BLA submissions, if specified criteria are met.

In addition to the Company's COVID-19 programs, in November 2025, the Company announced the selection of VBY329, a potential best-in-class mAb candidate being developed for the prevention of RSV infections in neonates, infants and children. The Company expects to advance VBY329 toward IND readiness in the second half of 2026. Through the Company's proprietary technology platform, the Company continues to investigate additional mAbs for protection and treatment of other important infectious diseases, such as measles. The Company is targeting identification of a preclinical mAb candidate for treatment and prevention of measles in the first half of 2026.

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 New Haven, Connecticut, and remotely. The Company leases dedicated laboratory and office space in Newton, Massachusetts for research and development purposes.

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, risks associated with market acceptance and commercialization 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.

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, proceeds from the Company's initial public offering ("IPO"), net proceeds received from shares of common stock sold under the Sales Agreement (as defined below) and net proceeds received from shares of common stock and pre-funded warrants sold under the Underwriting Agreements (as defined below). After receiving EUA in March 2024, the Company has also funded its operations from sales of PEMGARDA.

The Company has incurred recurring losses and negative cash flows from operations since its inception, including a net loss of $52.5 million for the year ended December 31, 2025. As of December 31, 2025, the Company had an accumulated deficit of $954.5 million. The Company may continue to generate operating losses for the foreseeable future.

Based on current operating plans and excluding any contribution from future 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. The accompanying consolidated financial statements do not include any adjustments related to the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the U.S. ("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 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 revenues and expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, research and development expenses and related prepaid or accrued costs, stock-based compensation expense, revenue, including discounts and allowances, and inventory obsolescence. The Company bases its estimates on historical experience, known trends, expected future internal sales forecasts 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. If actual market conditions are less favorable than those projected by management or in the event of an adverse FDA action, inventory write-downs may be required.

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 accounts receivable.

As of December 31, 2025, 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 two accredited financial institutions. 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 research and development programs. In particular, the Company relies on third-party contract manufacturers 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 a third-party contract manufacturer for 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 third-party organizations to supply it with its requirements for all product candidates. 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 commercialization of its product candidates and programs. Through December 31, 2025, the Company's research and development programs primarily relate to rights conveyed by Adimab, LLC ("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.

During the year ended December 31, 2025, the Company's net product revenue was generated from sales to third-party specialty distributors, infusion centers and healthcare providers in the U.S. (see "Revenue Recognition" for additional information). The following summarizes customers that represent 10% or greater of our consolidated total gross revenue:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Specialty distributor 1	46%	42%
Specialty distributor 2	23%	24%
Specialty distributor 3	17%	13%
Third-party logistic distribution agent	*	19%

* Represents less than 10% and/or not a customer in the applicable year

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.

Accounts Receivable, net

Accounts receivable, net as of December 31, 2025 consisted of $13.9 million of PEMGARDA product sales to third-party specialty distributors, infusion centers, healthcare providers and provider institutions. Three third-party specialty distributors accounted for 44%, 22% and 20%, respectively, of the Company's gross accounts receivable balance as of December 31, 2025. Three third-party specialty distributors accounted for 53%, 27% and 17%, respectively, of the Company's accounts receivable balance as of December 31, 2024. The Company evaluates the collectability of accounts receivable on a regular basis, by reviewing the financial condition and payment history of customers. As of December 31, 2025, the Company recorded an allowance for doubtful accounts of $0.3 million related to one direct customer.

Inventory

Prior to receiving regulatory approval or authorization, costs related to the manufacturing of inventory are recorded as research and development expense on the Company's consolidated statements of operations and comprehensive loss in the period incurred. In connection with the EUA for PEMGARDA in March 2024, the Company subsequently began capitalizing PEMGARDA inventory costs as it was determined that inventory costs incurred subsequent to the EUA had a probable future economic benefit.

Inventory is stated at the lower of cost or estimated net realizable value with cost determined on a first-in, first-out basis. Inventory costs include raw materials, third-party contract manufacturing, third-party packaging services, freight and overhead. The Company reduces its inventory to net realizable value for potentially excess, dated or obsolete inventory based on a quarterly assessment of the recoverability of its capitalized inventory. The Company periodically reviews inventory levels to identify what may expire prior to expected sale or has a cost basis in excess of its estimated realizable value and

writes-down such inventories as appropriate as a component of costs of goods sold in the consolidated statements of operations and comprehensive loss.

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 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, 2025 and 2024.

Leases

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, adjusted for prepaid rent payments. 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.

Pre-funded Warrants

The Company accounts for pre-funded warrants as equity-classified based on an assessment of the warrant's specific terms and applicable authoritative guidance included in Distinguishing Liabilities from Equity ("ASC 480") and Derivatives and Hedging ("ASC 815"). The assessment considers whether the pre-funded warrants are freestanding financial instruments pursuant to ASC 480, whether the pre-funded warrants meet the definition of a liability pursuant to ASC 480, and whether the pre-funded warrants meet all of the requirements for equity classification under ASC 815.

The Company's pre-funded warrants meet all of the criteria for equity classification and are recorded as a component of additional paid-in capital at the time of issuance, and are not remeasured.

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 reportable and operating 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.

Revenue Recognition

The Company recognizes revenue in accordance with ASC Topic 606 - Revenue from Contracts with Customers ("ASC 606"). Under ASC 606, an entity recognizes revenue when or as performance obligations are satisfied by transferring control of promised goods or services to the customer, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the

contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. At contract inception, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Product Revenue, Net

Following the Company's receipt of an EUA from the FDA for PEMGARDA in March 2024, the Company began generating product revenue from sales of PEMGARDA in April 2024.

The Company sells PEMGARDA in the United States primarily to third-party specialty distributors and directly to a small number of infusion centers, healthcare providers and provider institutions. Revenue is recognized when or as performance obligations are satisfied by transferring control of promised goods to a customer, generally upon delivery, based on an amount that reflects the consideration to which the Company expected to be entitled. The Company did not have any contract liabilities at December 31, 2025, as the Company did not receive any payments in advance of satisfying its performance obligations to its customers.

Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Discounts and Allowances

The Company records reserves, based on contractual terms, for the following components of variable consideration related to product sold during the reporting period, as well as its estimate of product that remains in the distribution channel inventory of its customers at the end of the reporting period, if applicable. On a quarterly basis, the Company updates its estimates, if necessary, and records any material adjustments in the period they are identified.

Trade Discounts, Group Purchase Organization and Distributor Fees

The Company provides customary discounts on PEMGARDA sales for prompt payment, the terms of which are explicitly stated in its contracts. The Company also pays fees to specialty distributors for sales order management, data, and distribution services, as well as fees to group purchasing organizations ("GPO") for administrative services, the terms of which are also explicitly stated in its contracts. Such fees are not for a distinct good or service and, accordingly, are recorded as a reduction of revenue, as well as a reduction to accounts receivable (trade discounts) or as a component of accrued expenses (distributor and GPO fees).

Chargebacks

The Company is subject to discount obligations under its contracts with the U.S. Department of Veterans Affairs and GPOs where pricing on PEMGARDA is extended below wholesaler list price to participating entities and GPO members. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability, which is included as a component of accrued expenses.

Product Returns

The Company offers a right of return for purchased units of PEMGARDA for damage, defect, recall, and/or product expiry, provided the product expiry is within a specified period as set forth in the Company's return goods policy. The Company estimates the amount of product sales that will be returned using quantitative and qualitative considerations. Reserves for estimated returns are recorded as a reduction of product revenue in the period that the related revenue is recognized, as well as a component of accrued expenses. To date, actual product returns have not differed materially from the Company's estimates.

Other Incentives

Other incentives include a co-pay assistance program for eligible patients with commercial insurance in the U.S. The co-pay assistance program assists certain commercially insured patients by reducing each participating patient's financial responsibility for the purchase price, up to a specified dollar amount of assistance.

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 contract 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, 2025.

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, 2025 and 2024.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For the years ended December 31, 2025 and 2024, the Company's only element of other comprehensive loss was foreign currency translation adjustments.

Net Loss per Share

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period. Diluted net 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 loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, including potential dilutive common shares.

As discussed in Note 10, the Company issued and sold pre-funded warrants to purchase up to an aggregate of 27,342,442 shares of common stock at an average purchase price of $1.5099 per pre-funded warrant (representing the average $1.51 per share purchase price less the exercise price of $0.0001 per pre-funded warrant share). Since the $0.0001 exercise price per pre-funded warrant share represents little consideration and is non-substantive in relation to the purchase price of $1.5099 per pre-funded warrant, and as the pre-funded warrants are exercisable at any time after their original issuance with no further vesting conditions or contingencies associated with them, the shares underlying the pre-funded warrants are therefore included in the calculation of basic net loss per common share.

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 December 31, 2026. 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 December 31, 2026. For so long as the Company remains an emerging growth company, it is permitted and intends to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. For example, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies.

In December 2023, the FASB issued ASU 2023-09, 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 the Company for the annual period beginning after December 15, 2024. The Company prospectively adopted ASU 2023-09 in the fourth quarter of 2025. Refer to Note 12 for additional information.

In November 2024, the FASB issued ASU 2024-03, Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses ("ASU 2024-03"). The new standard requires additional disclosure of the nature of expenses included in the income statement as well as disclosures about specific types of expenses included in the expense captions presented in the income statement. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The Company is currently evaluating the potential impact of ASU 2024-03 on its consolidated financial statement disclosures.

3. Fair Value Measurements

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

	Fair Value Measurements at December 31, 2025:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 224,172	$ —	$ —	$ 224,172
	$ 224,172	$ —	$ —	$ 224,172

	Fair Value Measurements at December 31, 2024:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents:				
Money market funds	$ 68,345	$ —	$ —	$ 68,345
	$ 68,345	$ —	$ —	$ 68,345

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, 2025 or 2024.

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, 2025 or 2024.

4. Inventory

The following table presents non-current inventories (in thousands):

	December 31, 2025	December 31, 2024
Work in process	$ 20,769	$ 20,769
Finished goods	4,730	5,138
	$ 25,499	$ 25,907

As of December 31, 2025, $0.3 million of finished goods inventory was classified as a current asset and included within prepaid and other current assets in the consolidated balance sheet. Please refer to Note 5 for additional information.

5. Prepaid Expenses and Other Current Assets

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

	December 31, 2025	December 31, 2024
Prepaid external research, development and manufacturing costs	$ 3,442	$ 15,264
Prepaid insurance	1,024	1,173
Other	1,454	3,726
Interest receivable	676	263
Finished goods inventory, current	263	—
	$ 6,859	$ 20,426

6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31, 2025	December 31, 2024
Accrued external research, development and manufacturing costs	$ 6,616	$ 41,680
Accrued professional and consultant fees	2,778	2,199
Accrued employee compensation	5,749	3,916
Accrued inventory	—	518
Other	3,910	1,884
	$ 19,053	$ 50,197

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, 2025 and 2024, 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. 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, 2025; however, milestone payments do not accrue for certain *in vitro* diagnostic devices consisting of or containing CoV Antibodies.

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, 2025.

During the years ended December 31, 2025 and 2024, the Company did not recognize any in-process research and development ("IPR&D") expense with respect to contingent consideration payable under the Adimab Assignment Agreement. Except for milestone payments of $11.1 million incurred through December 31, 2023, no other milestone payments have been paid to or have been earned by Adimab through December 31, 2025.

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"). During the year ended December 31, 2025, the Company expensed $2.1 million of royalties, while reserving all rights under the Adimab Assignment Agreement and the applicable law. During the year ended December 31, 2024, the Company expensed $1.0 million of royalties, while reserving all rights under the Adimab Assignment Agreement and the applicable law. 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.

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 experienced a change of control after the third anniversary of the Adimab Collaboration Agreement or (ii) Adimab owned 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 became obligated to pay Adimab a quarterly fee of $0.6 million. For both of the years ended December 31, 2025 and 2024, the Company recognized $2.4 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 both the years ended December 31, 2025 and 2024, 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 Collaboration Agreement. During the years ended December 31, 2025 and 2024, the Company did not recognize any IPR&D expense. 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, 2025 and 2024. 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, 2025, no royalty payments have been paid to or have been earned by 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 both the years ended December 31, 2025 and 2024, the Company recognized $2.0 million of R&D expense related to the annual fees. 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, 2025.

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, 2025, no royalty payments have been paid to or have been earned by 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, March 2024 and March 2026, 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 with respect to certain Licensed Products by making a one-time payment in the low eight-figures to WuXi Biologics and with respect to certain other Licensed Products by making a one-time payment in the middle-seven 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. The royalty obligation shall be waived to the extent the royalty obligation is derived or arising from a Licensed Product sold in the U.S. if the Company's ability to have such Licensed Product manufactured by WuXi Biologics becomes materially restricted due to certain government actions, with such waiver continuing for so long as such government action continues. Through December 31, 2025, 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, 2025 or 2024.

8. Population Health Partners, L.P.

In November 2022 (the "PHP Effective Date"), the Company entered into a Master Services Agreement with Population Health Partners, L.P. ("PHP"), pursuant to which PHP agreed to provide services and create deliverables for the Company as agreed between the Company and PHP and set forth in one or more work orders under such agreement (the "PHP MSA"). The term of the PHP MSA commenced on the PHP Effective Date for an initial term of one year. The PHP MSA renewed for subsequent periods, until terminated in accordance with its terms. The PHP MSA was terminated effective July 2024. 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 contained 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, 2025 and 2024, the Company did not recognize any 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 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 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. As of December 31, 2025, no portion of the PHP Warrant had vested.

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 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, which registration rights PHP exercised in January 2024.

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.

Tamsin Berry, a member of the Company's board of directors, is a Limited Partner of PHP.

9. Commitments and Contingencies

Operating Lease Commitments

In September 2021, the Company entered into a five-year facilities lease agreement for approximately 9,600 square feet of office space in Waltham, Massachusetts, which provides for monthly rental payments, including base rent charges of $0.4 million per year, subject to periodic rent increases, and the Company's proportionate share of operating expenses. The Company exercised its option to terminate and this lease agreement expired in accordance with its terms on May 31, 2025.

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"), which was amended in September 2022. Pursuant to the amended Newton, MA Lease, the Company entered into a two-year noncancelable agreement for new dedicated laboratory and office space in Newton, Massachusetts, on the same campus as, and in lieu of, the space leased under the original lease. The Company took occupancy of the new dedicated laboratory and office space in December 2022. The amended Newton, MA Lease provided for monthly rental payments, including base rent charges of $1.3 million per year. In August 2024 and May 2025, the Newton, MA Lease was further amended to extend the lease through December 2027, with an option to further extend the lease for an additional twenty-four months or continue the lease on a month-to-month basis after completion of the term ending in December 2027.

In February 2026, the Company further amended the Newton, MA Lease to add additional dedicated laboratory space, which commenced on March 1, 2026. The amendment provides for incremental annual base rent of $0.3 million for the remainder of the lease term, through December 2027. As the modification had not commenced as of December 31, 2025, no right-of-use asset or lease liability has been recorded in the accompanying financial statements.

In May 2025, the Company entered into a short-term lease agreement for approximately 13,600 square feet of office space in New Haven, Connecticut, with an original term of 12 months. The Company has elected the short-term lease recognition exemption under ASC Topic 842 – Leases and therefore has not recognized a right-of-use asset or lease liability on the balance sheet. As of December 31, 2025, base rent charges of less than $0.1 million were incurred.

In January 2026, the Company entered into an agreement to lease approximately 33,000 square feet of office space in New Haven, Connecticut. The term of the lease will commence after the later of (i) the date on which landlord improvements to the premises are deemed to be substantially completed, or (ii) the delivery of the lender consent package. The lease has an initial term of one hundred twenty-nine months, measured from the lease commencement date. The Company's obligation for the payment of rent for the premises begins six months after the lease commencement date and total future minimum lease payments are expected to be $10.9 million. The lease includes a tenant improvement allowance of approximately $1.0 million.

The New Haven, CT lease requires the Company to provide a security deposit of $1.0 million in the form of a letter of credit, which will be reduced by 50% following the first twelve months of rent payments.

As the New Haven, CT lease had not commenced as of December 31, 2025, no right-of-use asset or lease liability has been recorded in the accompanying financial statements.

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

	For the Year Ended December 31, 2025	For The Year Ended December 31, 2024
Lease cost:		
Operating lease cost	$ 1,468	$ 1,754
Variable lease cost	6	14
Total lease cost	$ 1,474	$ 1,768
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows related to operating leases	$ 1,335	$ 1,741

Future minimum lease payments under the noncancelable leases as of December 31, 2025 was as follows (in thousands):

Year Ending December 31,	Operating Lease
2026	$ 1,320
2027	$ 1,320
Total lease payments	2,640
Present value adjustment	(146)
Present value of operating lease liability	$ 2,494

As of December 31, 2025, 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 2.0 years.

As of December 31, 2024, 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 0.9 years.

The total operating liabilities are presented on the Company's consolidated balance sheet based on maturity dates. $1.3 million is classified under "operating lease liabilities, current" for the portion due within twelve months, and $1.2 million classified under "operating lease liabilities, non-current" as of December 31, 2025.

License Agreements

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

Manufacturing Agreements

In July 2020, the Company entered into a clinical Master Services Agreement with WuXi Biologics, which was amended in March 2026 (as amended, the "Clinical Master Services Agreement"). The Clinical Master Services Agreement outlines the terms and conditions under which WuXi Biologics coordinates biologics development and clinical manufacturing services for the Company.

In December 2020, the Company entered into a Commercial Manufacturing Services Agreement with WuXi Biologics, which was amended and restated in August 2021, further amended and restated in September 2023 and amended in March 2026 (as amended and restated and subsequently amended, 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, 2025, 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, 2025, the total remaining contractually binding commercial drug substance and drug product purchase obligations due to WuXi Biologics was $10.6 million, which was included in accounts payable and accrued expenses. The remaining contractually binding purchase obligation and was paid in January 2026.

During the year ended December 31, 2025, the Company committed to noncancelable purchase obligations related to the procurement of materials to be used in future drug substance and drug product manufacturing under the Commercial Manufacturing Agreement. As of December 31, 2025, the total remaining contractually binding purchase obligations due to WuXi Biologics was $3.5 million, which was included in accounts payable and accrued expenses. The remaining contractually binding purchase obligation was paid in January 2026.

Unless earlier terminated, the Commercial Manufacturing Agreement remains in effect until March 1, 2036, subject to renewal as may be agreed by the parties. 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. With advance notice, the Company may terminate the Commercial Manufacturing Agreement or an individual order for convenience. The Company may terminate the Commercial Manufacturing Agreement effective immediately if any new or existing law, rule, regulation, guideline or order prevents the Company from being able to enter into or maintain a contract with a U.S. governmental entity, or from receiving grant funds from such entity, or affects the Company's ability to obtain government insurance coverage of any product under the Commercial Manufacturing Agreement, in each case, as a result of WuXi Biologics providing services to the Company under the Commercial Manufacturing Agreement or being a party to the Commercial Manufacturing Agreement. 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, 2025 and 2024.

Legal Proceedings

From time to time, the Company may become involved in legal proceedings or other litigation relating to claims arising in the ordinary course of business. The Company accrues a liability for such matters when it is probable that future expenditures will be made and that such expenditures can be reasonably estimated. Significant judgment is required to determine both probability and estimated exposure amount. Legal fees and other costs associated with such proceedings are expensed as incurred. As of December 31, 2025, the Company was not a party to any material legal proceedings.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to its vendors, lessors, 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.

Loan Agreement

On April 18, 2025, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, as lender (the "Lender"). The Loan Agreement provides for a senior secured term loan facility in an aggregate principal amount of up to $30 million (the "Term Facility") consisting of (a) Term A Loans in an aggregate principal amount of up to $10 million, which shall be available to be drawn from and

after August 15, 2025 through December 31, 2026 upon compliance with certain financial covenants and conditions, (b) Term B Loans in an aggregate principal amount of up to $10 million, which shall be available to be drawn during the period commencing on the date of the achievement of certain net product revenue milestones and ending on June 30, 2027, and (c) Term C Loans in an aggregate principal amount of up to $10 million, which shall be available to be drawn during the period commencing on the date of the achievement of certain net product revenue milestones and ending on June 30, 2027. The proceeds of the Term Facility may be used for working capital and general business purposes. As of December 31, 2025, the Company had not satisfied certain financial covenants and conditions, including the net product revenue milestone required to be eligible to access proceeds from the Term Facility. Accordingly, as of December 31, 2025, no amounts have been drawn down under the Loan Agreement.

The loans under the Term Facility are due and payable on March 1, 2029 and bear interest that is payable monthly, commencing with the month in which any loans are funded under the Term Facility, in arrears at a per annum rate, subject to increase during an Event of Default (as defined in the Loan Agreement), equal to the greater of (x) the Wall Street Journal prime rate minus 0.25%, subject to a 9.00% cap, and (y) 6.00%. Commencing on April 1, 2027, which date may be extended to April 1, 2028 upon the achievement of certain net product revenue milestones (the "Interest-Only Period Extension"), the Company will be required to repay the principal of the Term Facility in 24 consecutive equal monthly installments or, in the case of the Interest-Only Period Extension, 12 consecutive equal monthly installments. At maturity, or if earlier prepaid, the Company will also be required to pay a final payment fee equal to 4.50% of the aggregate principal amount of the loans advanced under the Term Facility. The Loan Agreement provides for an unused term loan commitment fee equal to 1.00% of the Term Facility upon the earliest to occur of (a) July 1, 2027, (b) the occurrence of an Event of Default under the Loan Agreement and (c) the termination of the Loan Agreement; provided, that such fee will be waived by the Lender in the event that the Company has requested and the Lender has funded any loans under the Term Facility prior to such date.

10. Common Stock

Shares Reserved for Future Issuance

As of December 31, 2025 the Company had reserved 36,121,835 shares of common stock for the exercise of outstanding stock options, the vesting of outstanding restricted stock units ("RSUs") 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 and an 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 (the "2022 Shelf Registration Statement"). The 2022 Shelf Registration Statement expired upon the effectiveness of the 2025 Shelf Registration Statement (as defined below).

In October 2025, the Company filed a new shelf registration statement on Form S-3 with the SEC and an accompanying base prospectus, which was declared effective by the SEC on December 23, 2025, for the offer and sale of up to $350 million of the Company's securities (the "2025 Shelf Registration Statement"). As of December 31, 2025, excluding the $75 million allocated to the 2025 ATM Prospectus Supplement (as defined below), $275 million of the Company's securities remained available for offer and sale under the 2025 Shelf Registration Statement.

August 2025 Underwritten Public Offering

In August 2025, the Company completed an underwritten public offering pursuant to an underwriting agreement (the "August Underwriting Agreement") with Cantor Fitzgerald & Co. ("Cantor"), as representative of the underwriters named therein, pursuant to which it issued and sold an aggregate of 89,234,480 shares of its common stock at a price of $0.52 per share, and pre-funded warrants to purchase up to an aggregate of 21,342,442 shares of common stock at a price of $0.5199 per pre-funded warrant (the "August 2025 Underwritten Public Offering"). The price of $0.5199 per pre-funded warrant represented the $0.52 per share purchase price for the common stock less the exercise price of $0.0001 per pre-funded warrant. The pre-funded warrants are exercisable at any time after their original issuance and will not expire. The Company

received total net proceeds of approximately $53.5 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. As of December 31, 2025, there were no exercises of pre-funded warrants.

November 2025 Underwritten Public Offering

In November 2025, the Company completed an underwritten public offering pursuant to an underwriting agreement (the "November Underwriting Agreement" and together with the August Underwriting Agreement, the "Underwriting Agreements") with Cantor, as representative of the underwriters named therein, pursuant to which it issued and sold an aggregate of 44,000,000 shares of its common stock at a price of $2.50 per share, and pre-funded warrants to purchase up to an aggregate of 6,000,000 shares of common stock at a price of $2.4999 per pre-funded warrant (the "November 2025 Underwritten Public Offering", and, together with the August 2025 Underwritten Public Offering, the "2025 Underwritten Public Offerings"). The price of $2.4999 per pre-funded warrant represented the $2.50 per share purchase price for the common stock less the exercise price of $0.0001 per pre-funded warrant. The pre-funded warrants are exercisable at any time after their original issuance and will not expire. The Company received total net proceeds of approximately $117.2 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company. As of December 31, 2025, there were no exercises of pre-funded warrants.

In December 2025, and in connection with the November 2025 Underwritten Public Offering, Cantor exercised the option pursuant to the November Underwriting Agreement to purchase 4,675,000 additional shares of common stock at the public offering price of $2.50, less underwriting discounts and commissions. In connection with such exercise, the Company received total net proceeds of approximately $10.9 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

ATM Facility

In December 2023, the Company entered into a Controlled Equity Offering^{SM} Sales Agreement (the "Sales Agreement") with Cantor, as sales agent and filed with the SEC a prospectus supplement to the 2022 Shelf Registration Statement (the "2023 ATM Prospectus Supplement"), pursuant to which the Company could, 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 of 1933, as amended (the "Securities Act"). Cantor was entitled to a commission of 3% of the gross proceeds from any sales of such shares. In 2024, the Company sold 9,000,000 shares of its common stock under the Sales Agreement and the 2023 ATM Prospectus Supplement, at an average price of $4.50 per share for $39.3 million in proceeds net of commissions. In 2025, the Company sold 23,055,402 shares of its common stock under the Sales Agreement and the 2023 ATM Prospectus Supplement at an average price of $1.49 per share for $33.4 million in proceeds net of commissions. Upon the effectiveness of the 2025 Shelf Registration Statement, all offers and sales under the 2023 ATM Prospectus Supplement were deemed terminated.

In October 2025, in connection with the filing of the 2025 Shelf Registration Statement, the Company filed with the SEC a new prospectus supplement (the "2025 ATM Prospectus Supplement"), 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 2025 Shelf Registration Statement was declared effective by the SEC on December 23, 2025, and $75.0 million remained available for sale under the 2025 ATM Prospectus Supplement as of December 31, 2025.

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, 2025, there were 467,615 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 December 2024, the 2021 Plan was amended by Amendment No. 1 to the 2021 Plan, which decreased the aggregate number of shares of the Company's common stock reserved for issuance under the 2021 Plan by 8,000,000 shares. 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. On January 1, 2024, 3,304,820 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. On January 1, 2026, 14,099,351 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 number of shares to be issued under the 2021 Plan did not increase pursuant to the evergreen provision thereof on January 1, 2023 nor January 1, 2025, 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, 2025, there were an aggregate of 35,609,897 shares authorized to be issued under the 2020 Plan and the 2021 Plan, which included 467,615 and 22,423,326 shares authorized to be issued upon the exercise of outstanding stock option grants from the 2020 Plan and 2021 Plan, respectively, and 0 and 12,718,956 shares reserved for future issuance under the 2020 Plan and 2021 Plan, respectively.

2026 Inducement Plan

In January 2026, the Company's board of directors adopted the 2026 Inducement Plan (the "2026 Inducement Plan"). Under the 2026 Inducement Plan, the Company is authorized to issue up to 8,000,000 shares pursuant to inducement grants. The only persons eligible to receive grants under the 2026 Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq Listing Rule 5635(c)(4) and the related guidance under Nasdaq IM 5635-1, including individuals who were not previously an employee or director of the Company (or individuals following a bona fide period of non-employment), in each case as an inducement material to such individual's agreement to enter into employment with the Company. The 2026 Inducement Plan provides for the discretionary grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance awards, and certain other awards.

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:

	For the Year Ended December 31, 2025	For the Year Ended December 31, 2024
Expected term (in years)	5.8	5.9
Expected volatility	61.8%	62.4%
Risk-free interest rate	4.2%	4.1%
Expected dividend yield	—%	—%

Stock Option Activity

The following table summarizes the Company's stock option activity since December 31, 2024:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	14,987,559	$ 4.51	7.5	$ —
Granted	12,168,094	$ 1.48		
Exercised	(292,273)	$ 1.41		
Forfeited	(5,511,439)	$ 4.01		
Outstanding at December 31, 2025	21,351,941	$ 2.96	8.1	$ 15,525
Vested and expected to vest at December 31, 2025	21,351,941	$ 2.96	8.1	$ 15,525
Options exercisable at December 31, 2025	9,823,931	$ 4.47	7.1	$ 4,791

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $0.89 and $1.88, 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, 2025 and December 31, 2024.

The total intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was $0.2 million and $0.4 million, respectively.

Restricted Stock Unit Activity

In February and September 2025, the Company's board of directors approved RSU grants to the Company's executive officers and certain of its employees under the 2021 Plan. In February, an aggregate of 1,700,000 RSUs were issued at a grant date fair value of $1.61 per share. In September 2025, an aggregate of 400,000 RSUs were issued at a grant date fair value of $1.15 per share. All RSU grants are scheduled to vest over an eighteen-month period, with one-third of the RSUs vesting every six months following the relevant grant date, subject to continuous service as of each vesting date.

The following table summarizes the Company's RSU activity since December 31, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested at December 31, 2024	—	$ —
Granted	2,100,000	$ 1.52
Vested	(561,000)	$ 1.61
Forfeited	—	$ —
Unvested at December 31, 2025	1,539,000	$ 1.49

Stock-Based Compensation Expense

The Company recorded stock-based compensation expense (service-based stock options, RSUs and the Company's employee stock purchase plan) in the following expense categories of its consolidated statements of operations and comprehensive loss (in thousands):

	For the Year Ended December 31, 2025	For the Year Ended December 31, 2024
Research and development	$ 3,037	$ 4,980
Selling, general and administrative	8,606	14,808
	$ 11,643	$ 19,788

As of December 31, 2025, total unrecognized stock-based compensation expense related to unvested options was $11.2 million, which is expected to be recognized over a weighted-average period of 2.2 years.

As of December 31, 2025, total unrecognized stock-based compensation expense related to unvested RSUs was $1.5 million, which is expected to be recognized over a weighted-average period of 0.77 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 830,835 shares issued under the 2021 ESPP as of December 31, 2025. 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 pursuant to the evergreen provision thereof on January 1, 2023, January 1, 2024, nor January 1, 2025, as determined by the Company's board of directors. On January 1, 2026, the number of shares to be issued under the 2021 ESPP increased by 2,685,546 shares of common stock, pursuant to the evergreen provision thereof. The first offering under the 2021 ESPP was June 6, 2022. As of December 31, 2025, 511,938 shares remained available for issuance under the 2021 ESPP. During the years ended December 31, 2025 and 2024, the Company recognized $0.2 million and $0.1 million, respectively, in related stock-based compensation expense.

Warrant Expense

In November 2022, the Company entered into the PHP MSA, the PHP Work Order and a warrant agreement with respect to the PHP Warrant. To compensate for the services and deliverables provided by PHP, the Company issued 6,824,712 equity-classified warrants to PHP. Each warrant shall give the right to acquire common stock of the Company at a purchase price of $3.48 per share. Per the agreement, the PHP Warrant is exercisable upon either the achievement of corresponding market capitalization targets or a consummation of a fundamental transaction (as defined in the PHP Warrant); as such, there are no other requirements, including any continuous service requirements, in order for PHP to be entitled to the PHP Warrant, if and when any portion of it vests.

The 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.

Other than the pre-funded warrants issued in the 2025 Underwritten Public Offerings, there were no warrants issued during the years ended December 31, 2025 and December 31, 2024.

As of December 31, 2025, other than the pre-funded warrants issued in the 2025 Underwritten Public Offerings, there were 6,824,712 warrants outstanding and not yet vested at a weighted average exercise price of $3.48, with a weighted-average remaining contractual term of 6.88 years.

12. Income Taxes

During the years ended December 31, 2025 and 2024, 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.

As further described in Note 2, the Company has elected to prospectively adopt the guidance in ASU 2023-09. The following table is a reconciliation of the effective income tax rate to the statutory federal income tax rate for the year ended December 31, 2025 in accordance with the guidance in ASU 2023-09:

	Year Ended December 31, 2025	
	Amount	Percent
	(in thousands)	
U.S. federal taxes at statutory rate	$ (11,019)	21.0%
Foreign tax effects		
Other	25	—
Tax credits		
Federal R&D tax credits	(1,799)	3.4
Changes in valuation allowances	11,751	(22.4)
Nontaxable or nondeductible items		
Stock-based compensation	682	(1.3)
Other	283	(0.5)
Other adjustments	77	(0.2)
Effective income tax rate	$ —	—%

The following table is a reconciliation of the Company's effective income tax rate to the statutory federal income tax rate for the year ended December 31, 2024:

	Year Ended December 31, 2024
Federal statutory income tax rate	(21.0)%
State income taxes, net of federal benefit	(3.3)
Federal research and development tax credits	(2.4)
Stock-based compensation	0.4
Change in deferred tax asset valuation allowance	26.0
Other	0.3
Effective income tax rate	—%

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

	Year Ended December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 119,103	$ 97,344
Capitalized research and development	74,352	91,954
Research and development tax credit carryforwards	30,928	28,664
Stock-based compensation expense	18,868	17,576
Warrant expense	4,319	4,497
Intangibles	3,265	3,695
Operating lease liabilities	620	338
Other	1,496	881
Total gross deferred tax assets	252,951	244,949
Valuation allowance	(252,232)	(244,457)
Total deferred tax assets	719	492
Deferred tax liabilities:		
Operating lease right-of-use assets	(607)	(358)
Depreciation expense	(112)	(134)
Total deferred tax liabilities	(719)	(492)
Total net deferred tax assets	$ —	$ —

As of December 31, 2025 and 2024, the Company had U.S. federal NOL carryforwards of $485.8 million and $392.0 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, 2025, the Company had state NOL carryforwards of $286.9 million, which may be available to reduce future taxable income, of which $41.8 million have an indefinite carryforward period while the remaining $245.1 million begin to expire in 2031. As of December 31, 2025, the Company also had U.S. federal and state research and development tax credit carryforwards of $24.8 million and $7.7 million, respectively, which may be available to reduce future tax liabilities and expire at various dates beginning in 2040 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, 2025 and 2024. Management reevaluates the positive and negative evidence at each reporting period. During the years ended December 31, 2025 and 2024, the Company increased its valuation allowance by $7.8 million and $44.1 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 following table presents the Company's change in valuation allowance for the years ended December 31, 2025 and 2024 (in thousands):

	Years Ended December 31,	
	2025	2024
Valuation allowance at the beginning of the year	$ 244,457	$ 200,385
Increase (decrease) for the current period	7,775	44,072
Valuation allowance at the end of the year	$ 252,232	$ 244,457

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, 2025 and 2024, 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. Income taxes paid, net of refunds received, were immaterial for the year ended December 31, 2025.

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 the years ended December 31, 2025 and 2024, the Company contributed $0.8 million and $0.6 million to the 401(k) Plan, respectively.

14. Net Loss per Share

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

	Year Ended December 31, 2025	Year Ended December 31, 2024
Numerator:		
Net loss attributable to common stockholders	$ (52,489)	$ (169,925)
Denominator:		
Weighted-average common shares outstanding, basic and diluted	172,212,902	118,555,073
Net loss per share attributable to common stockholders, basic and diluted	$ (0.30)	$ (1.43)

The 27,342,442 shares of common stock issuable upon exercise of pre-funded warrants described in Note 10 are included as outstanding common stock in the calculation of net loss per share.

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:

	For the Year Ended December 31, 2025	For the Year Ended December 31, 2024
Stock options to purchase common stock	21,351,941	14,987,559
Restricted stock units	1,539,000	—
Warrants to purchase common stock	6,824,712	6,824,712
	29,715,653	21,812,271

15. Related-Party Transactions

As of December 31, 2025 and 2024, an aggregate of $0.7 million and $1.3 million, respectively, was due to Adimab, a beneficial owner of more than 5% of the Company's common stock, under the Adimab Assignment Agreement, the Adimab Collaboration Agreement, the Adimab Platform Transfer Agreement, the Adimab DNA Sequencing Services Agreement and the Adimab LCMS Services Agreement (as defined below) by the Company and was included in accrued expenses. As of December 31, 2025 and 2024, no amounts were due to the Company from Adimab under the Adimab Assignment Agreement, the Adimab Collaboration Agreement, the Adimab Platform Transfer Agreement, the Adimab DNA Sequencing Services Agreement or the Adimab LCMS Services Agreement.

Adimab Assignment Agreement

Under the Adimab Assignment Agreement, Adimab 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 years ended December 31, 2025 and 2024, the Company did not recognize any IPR&D expense with respect to contingent consideration payable under the Adimab Assignment Agreement.

During the years ended December 31, 2025 and 2024, 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, 2025, the Company expensed $2.1 million of royalties as costs of product revenue, while reserving all rights under the Adimab Assignment Agreement and the applicable law. During the year ended December 31, 2024, the Company expensed $1.0 million of royalties as costs of product revenue, while reserving all rights under the Adimab Assignment Agreement and the applicable law.

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 the years ended December 31, 2025 and 2024, the Company recognized $2.4 million of research and development expense related to the quarterly fee under the Adimab Collaboration Agreement.

During the years ended December 31, 2025 and 2024, 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 Collaboration Agreement.

During the years ended December 31, 2025 and 2024, the Company did not recognize any IPR&D expense related to drug delivery fees, optimization completion fees or option exercise fees.

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), including an annual fee of single digit millions on each of the first four anniversaries of the Adimab Platform Transfer Agreement Effective Date.

During both the years ended December 31, 2025 and 2024, the Company recognized $2.0 million of research and development expense related to the annual fee 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 both the year ended December 31, 2025, and 2024, 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.

Adimab LCMS Services Agreement

In November 2023, as amended in December 2025, the Company entered into a Services Agreement with Adimab for Adimab to provide molecular weight determination services and deliver to the Company the resulting data and information (the "Adimab LCMS Services Agreement"). In exchange for the services performed, the Company will pay Adimab a fee for each sample tested.

During the year ended December 31, 2025, 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 LCMS Services Agreement. During the year ended December 31, 2024, 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 LCMS Services Agreement.

16. Segment Reporting

The Company operates as a single reportable and operating segment dedicated to the research and development, commercialization, and sale of mAbs in the U.S to deliver protection from serious viral infectious diseases.

The determination of a single reportable segment is consistent with the consolidated financial information regularly reviewed by the Chief Operating Decision Maker (the "CODM") in assessing performance and deciding how to allocate resources on a consolidated basis. The CODM is the Principal Executive Officer, who also serves as the Chief Financial Officer.

The CODM assesses performance and allocates resources based on the Company's net loss reported on the consolidated statements of operations and comprehensive loss. The CODM's area of focus is period over period fluxes and budget-to-actual variances when assessing performance and deciding how to allocate resources. The Company's reportable segment derives its revenues from sales of its product, PEMGARDA. No asset information has been provided for the reportable segment as the CODM does not regularly review asset information by reportable segment.

The following table presents information about reported segment revenues, and significant segment expenses as provided to the CODM (in thousands). Certain prior period segment expense amounts have been recast to reflect the current year presentation.

	Year Ended December 31, 2025	Year Ended December 31, 2024
Revenue:		
Product revenue, net	$ 53,426	$ 25,384
Total revenue	53,426	25,384
Operating costs and expenses:		
Cost of product revenue	3,747	1,618
Research and development expense		
Direct, external research and development expenses by program:		
Pemivibart[1]	3,140	31,757
VYD2311[2]	4,597	67,505
VBY329[3]	615	—
Early-stage programs	428	974
Total direct, external research and development expenses by program	8,780	100,236
Personnel expense (research and development)	11,746	16,294
Stock-based compensation (research and development)	3,037	4,980
Other research and development expenses	14,745	15,744
Total research and development expenses	38,308	137,254
Selling, general and administrative expense		
Sales and Marketing costs	13,786	15,990
Personnel expense (selling, general and administrative)	22,651	15,101
Stock-based compensation (selling, general and administrative)	8,606	14,808
Other selling, general and administrative expenses	21,888	17,489
Total selling, general and administrative expenses	66,931	63,388
Total operating costs and expenses	108,986	202,260
Loss from operations	(55,560)	(176,876)
Other income:		
Other income, net[4]	3,071	6,951
Total other income, net	3,071	6,951
Net loss	$ (52,489)	$ (169,925)

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

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

(3) In November 2025, the Company announced the nomination of VBY329 as an RSV mAb candidate for preclinical development.

(4) Includes interest income of $3,107 and $7,216 for the years ended December 31, 2025 and 2024, respectively.